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Abstract

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(U) This report supplies information and evaluation of Soviet developments and application in the area of alloplasty and alloplastic materials. The general field of biostimulation and bioelectric control as applied to various prosthetic devices are discussed, as well as the application from these areas to future developments, not only in various aspects of clinical medicine, but also in industrial, commercial, and training situations, as well as to certain areas of aerospace operations.

## FOREIGN TECHNOLOGY REPORT

## FOREIGN DEVELOPMENTS IN PROSTHETICS

June 1966

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PREFACE

## 1. PURPOSE

This report is an unscheduled product prepared by the Technical Evaluation and Application Directorate, Deputy for Foreign Technology, Aerospace Medical Division. This report furnishes collected information on the current state-of-the-art in Soviet achievements, capabilities, problems, and trends in various aspects of alloplasty, surgical prosthesis, and orthopedic appliances. The product supports AMD Task 718407 (U) Design Criteria for Nuclear Systems Support Equipment and AMD Project 7756 (U) Air Force Clinical Medicine.

## 2. SCOPE

This report is based on selected material from unclassified information in these areas available to the Deputy for Foreign Technology.

## 3. SECURITY

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FOR THE COMMANDER

  
ROBERT B. PAYNE, Colonel, USAF, BSC  
Deputy for Foreign Technology



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## SUMMARY

The Soviets are gaining considerable experience in the broad field of alloplasty, as well as in the design, construction, and application of equipment for artificial circulation, oxygenation, hypothermia, and hemodialysis. In the latter areas they seem to be suffering from a lack of technical and professional competence, as well as from poor materials and construction technology.

The Soviets have introduced two new designs for the construction of artificial heart valves, a teflon-flap type and a segmented spherical model. Both of these deserve long-term clinical evaluation.

Soviet technology in prosthetics development, particularly in the area of orthopedic appliances, is now firmly based on principles of biochemical, biophysical, and bioenergetic control. Achievements in this area include biostimulators for physiotherapeutic applications, as well as for long-term developments in training and performance of various tasks, as in aerospace operations, through remote use of bioelectric control systems.

Greatest Soviet advances have been made in the design and construction of bioelectrically controlled prostheses for both upper and lower extremities. The ease of operation of even these prototypes is in sharp contrast to the fatiguing use and extensive training requirements of most current conventional prostheses.

## INTRODUCTION

"Each animate organism is a complex individualized system whose internal forces maintain equilibrium with the external forces of the environment every moment of its existence as such....A time is coming, however remote it may be, when mathematical analysis, proceeding from natural-scientific analysis, will embrace all these equilibrations with grand formulas of equations, including in them, finally even itself."

I. P. Pavlov, 1938

Purpose

The purpose of this report is to discuss and evaluate foreign, chiefly Soviet, developments, achievements, capabilities, and trends in the area of prosthesis and prosthetics. These terms will be further defined in their changing perspective and relationship to the broad area of automation and other emerging technologies. A treatment of the theoretical and practical aspects of the evolution of prosthesis, and of Soviet management, organization, and facilities for prosthetics development concludes the Introduction.

The main sections of the report are devoted to the major areas of surgical prosthesis, alloplasty and prosthesis, as defined in each of those sections. These discussions are followed by an evaluation of Soviet developments, with a comparison of Western trends and achievements.

During the past few years, much emphasis has been placed on the overwhelming complexity of the tasks that man must accomplish if he and his culture and civilization are to survive, particularly in reference to space and other exploration and to his relation with the other nations of the world. Man has been in a continual struggle with his environment in order to survive. He has adapted himself to this problem through enhanced physical mobility and manual dexterity. In this struggle, the broad base of prosthetics has been used, among other things, to compensate for and correct deficiencies brought about by injury and disease. During the past few decades, particularly since World War II, there have been tremendous impetus and effort by man to develop machines and instruments which can assist him in his daily tasks. Many of these machines are entirely external to man and are operated either by him or by his command. These

machines are extensions of man's abilities to accomplish tasks of which he is otherwise physically and mentally incapable, in terms of insufficient power, speed, frequency, sensitivity, selectivity, reliability, accuracy, and so forth. All of these devices belong to the general class of tools, including automatic or mechanical machines. This class is comprised of tools and appliances based on such technologies as cybernetics, bionics, and biotics. Bionics and biotics are mutually exclusive, by definition, while either may or may not incorporate cybernetic principles. In turn, cybernetic devices may be automatic, bionic, or biotic.

In the development of automatic devices to extend human performance capabilities, great emphasis has been placed on the most complex of all known bionic and biocybernetic devices--the living organism. One of the directions which this development has taken has been the reproduction, duplication, and simulation of animal and plant functions themselves. This last statement defines bionics. It has also been logical to assume that a device which resembles the animal or plant part in shape, size, and internal structure is probably the most efficient one; however, this is not always true.

Within this general realm of bionics is a large area concerned with the temporary restoration or permanent replacement of a missing part or defective function of the human body, by means of an artificial, mechanical, nonliving device. This area may also be called medical or clinical bionics, but it is usually called prosthetics, and the device itself, as well as its actual restoration or replacement, is called a prosthesis. Webster's Unabridged Dictionary (1) defines prosthesis as "an artificial device to replace a missing part of the body." Dorland's Illustrated and other medical dictionaries (2,3) include in the definition the actual replacement of the part. This paper will be concerned with both aspects, as delineated below.

### Scope

By definition, prostheses replace body parts. The purpose of replacement is to provide the biologic function of the replaced part. The ideal prosthesis is one which is structurally similar and functionally identical to the replaced part, except that it is made entirely of nonliving materials. Whether the replacement is a bionic or biocybernetic unit (and it must be one or the other) will depend entirely on its function relative to those of other parts. If it is merely passive or supportive, as the replacement of a femur or patella, it is



bionic. If it responds to external stimuli and changes in its environment, as for example an artificial kidney, then it is more or less biocybernetic. In contrast, one may note here that biologic or living tissue or organ transplants are biotic units.

The ingenuity of man is not yet such that he can construct an artificial kidney 2 x 3 x 4 inches for permanent or even temporary replacement of a missing or defective organ. He has been able, on the other hand, to make an apparatus which performs many of the functions of the kidney--e.g., hemodialysis. This is also true of heart-lung machines, pump oxygenators, and other similar devices. We can therefore divide prosthetic devices into two groups, according to the definition above--restorative devices and replacement devices. The latter are usually permanent, while the former are most often temporary. Many of the former have been used during various surgical and other procedures in order to remove the burden of function temporarily from certain injured or weakened parts, usually for the purpose of surgical repair.

The term prosthesis is used in a very broad sense today in both the United States and Russia. It is therefore necessary to define prosthetics, for the purpose of this report, in terms of what it is not as well as of what it is, in order to limit the discussion. Dentures, artificial teeth, bridges, and other products of the prosthodontists' art are excluded, as are certain electronic devices and transducers which can be implanted more or less permanently in various tissues for the sole purpose of detecting bioelectric and biochemical signals. We are not interested here in certain simple replacements and restorations, such as metal plates to replace, for example, the bones of the skull. The discussion will be oriented toward those devices which actively simulate or reproduce biologic functions, rather than those which play purely passive or supportive roles.

### Historical Background

The first prosthetic device used by man was most probably a branch from a tree, which he used as a crutch for a broken or injured leg. Anthropologic data lead us to believe that the use of splints came much later in the history of man. From the crutch to the peg leg was only a short step, although it probably required thousands of years. This device might more elegantly be termed a crude form of a below-the-knee prosthesis. Later developments along these lines took the form

of the "hook," a familiar sight for many hundreds of years, especially in Asiatic countries, where it frequently appeared as a necessary consequence following the amputation of a hand as a punishment for theft and other crimes. As the peg leg functioned to support in the manner of the lower leg and foot, so the hook functioned to grasp or hold in the manner of the fingers.

The restorative dental materials developed during the late 17th and early 18th centuries, and continuing down to the present time, form a logical link in the sequential development of prostheses. These efforts were crude, indeed, but they served mankind until some time between the two World Wars. One might also mention glass "eyes," doubtless in use at the beginning of this era, which functioned more for the comfort of the beholder than of the wearer.

War has been man's predominant occupation throughout history, and has afforded numerous opportunities for the development of prosthetic devices. Nor have the degenerative diseases, which cripple man in body and spirit, changed significantly throughout recorded history, although perhaps emphasis has shifted from time to time and from clime to clime. Wars were generally petty, in terms of lost lives and maimed bodies, up to World War I. That great slaughter gave tremendous impetus to medical and surgical research in reconstructive and restorative surgery. The advances in medicine and surgery between the two Wars, especially in the United States, found us not entirely unprepared in the early 1940's. The casualties came back rapidly and in great numbers across the Atlantic and the Pacific, and the range of functional and structural loss was staggering. In our own country and those of our allies, however, we were aware of the use, for example, of steel and other types of metallic wires and banks to replace tendons and ligaments in hands, wrists, feet, and so forth. Most of these devices were meant to be only temporary replacements, in order to stretch and strengthen atrophied muscles, tendons, and ligaments until they could once more function for themselves.

In sharp contrast to our own relatively current technology in both medicine and surgery at that time, the Soviet Union found itself limited largely to 18th and 19th century medical and surgical lore. This was due largely to the failure of the Soviet regime, following its inception in 1917, to supply either encouragement, official recognition, or tangible support for surgical facilities and research, which



in turn led during the next 25 years to a gross gap in their ability to achieve the necessary contemporary state of the art.

The postwar wave of technologic and economic advances enabled us to build bigger, faster, and more automobiles and thus continue the wartime injury rate, and frequently to exceed it. Aside from this, surgical research in this country and abroad turned once again to man's age-old problems of growing old, of worn-out and injured parts, tissues, and organs, and of hereditary, congenital, and traumatic defects. In these fields physicians and surgeons now concentrated a large proportion of their attention, resources, and efforts.

The continued development of prosthetic devices in the United States and Russia today appears to represent an almost complete dichotomy of medical philosophy and emphasis. In one sense this is true, although it is becoming less so. American medicine sets and has always set a standard which is second to none. American prosthetics research and development reached a high level in the two decades following World War I and, based on existing technology, was unequalled. This technology enabled American manufacturers, through close cooperation and guidance from orthopedists and others, to build and market highly serviceable and extremely well designed mechanical prosthetic appliances, particularly those for the upper and lower extremities, both total and partial. These were operated by the subject through the application of isometric contractions of remaining muscle groups--viz., those of the shoulder, back, and hip. These devices rendered rehabilitation and physiotherapy a tedious and frustrating task, through the long periods required for retraining and the frequent fatigue involved. The state-of-the-art at that time, however, did not extend beyond the application of musculoskeletal mechanics to these devices.

Soviet prosthetics between the Wars, on the other hand, was hardly given any priority in the face of other national problems, and in fact, did not begin to emerge, except in isolated instances, until well after the end of World War II. When it finally did emerge, it was based, like other Soviet endeavors, on a cooperative synergism of many sciences--medicine, surgery, mechanics, biophysics, electronics, etc. Moreover, it leaned heavily for its initial development on prior American and other Western achievements. One of the reasons for this divergence of development was the failure or belated application in the United States of developments in electronics during World War II to the problems of medicine and surgery. This

cultural and technologic lag was due to the fact that the United States already had a satisfactory technology in prosthetics in being. Thus, the technology existing after World War II resulted in resistance to the introduction and application of newly emerging scientific concepts and disciplines into the area of prosthetics. During the past 20 years there has been, for example, a tremendous surge of effort in the field of biophysics, a science which can best be defined as the study of the physical properties, functions, and reactions of living systems, from the lowest subcellular level to that of the entire organism. In this way biophysics is analogous to biochemistry. Biochemistry was not fully accepted as an adjunct to the medical sciences until after 1920, although it had its origins in the mid-19th century, or perhaps even earlier.

It is now a matter of common knowledge that developments in prosthetics during the first half of this century were in some respects biocybernetic and bionic. But the organized body of scientific theory on which to base further developments along these lines were not forthcoming until just before mid-century, when they were expounded in the writings of Norbert Weiner and others. This theoretical approach to practical applications of systems control concepts was directly in line with Soviet philosophy, and in their headlong pursuit of long-term goals and programs they were more than willing to give any such material technology a try. Moreover, Pavlovian concepts of biologic activities and the keys to further knowledge of these activities clearly stated that these lay in the realm of physiologic control mechanisms--i.e., biochemical and biophysical mechanisms.

Soviet technology, which through the end of World War II was largely on an academic footing, has within the past decade given full approval and tangible support of, ironically enough, theories of automation that were developed initially in the United States. One notes particularly the emergence of cybernetic applications to Soviet organization, management, and research only after 1955. The establishment in 1957 of the Scientific Council for the Coordination of the Complex Problems of Cybernetics placed this concept on a party-approved basis throughout the Soviet Union. One should note also, in this regard, the relatively recent establishment of the Institute of Biophysics in the Academy of Sciences of the USSR. Biophysics research in the United States is still largely limited to so-called "pure" physiologic research, or to the role of a laboratory curiosity in a few medical schools. American developments in bio-



cybernetics and bionics as applied to medicine and surgery are undeniable, yet they have stopped short in an area which could prove most fruitful. The general absence of more efficient prosthetic appliances in this country is supported by the lack of research on the part of almost all American prosthetics manufacturers (see page ), who cannot or will not allocate the sums of money necessary for developmental research in this area because the results of their efforts will in the long run be too expensive for a large proportion of the potential using population. This is all the more surprising when one views with considerable satisfaction the development and widespread use in this country of a large variety of surgical and medical equipment, based on principles of automation, cybernetics, and bionics, which are currently available and under expensive research programs for further developments.

In the Soviet Union, biophysics has become another one of the sciences which presents a concept of biology and biologic function that has great appeal to the Russian scientific community, first, because it provides diverse scientific disciplines a common groundbase for the application of modern scientific and technologic concepts to problems in biology and medicine, and, more important, because it has been accepted into the framework of communist party dogma. It was thus possible for Soviet medical research to proceed apace in the development and application of prosthetic appliances based on biophysical principles, while in the United States prosthetics was and still is largely based on purely physical principles. While initial applications of cybernetic theory were not in the fields of biology and medicine, developments in other areas soon provided impetus and direction in the clinical and allied sciences. Within the short span of 10 years, numerous medical and surgical facilities devoted almost entirely to the development of prosthetic devices were established in the Soviet Union (see below). Moreover, areas which once supplied theory and applications as by-products to medicine and surgery now themselves received the benefits of direct developments in these two fields. Thus, the entire effort in prosthetics and its closely allied fields of bionics, biocybernetics, and biostimulation now are gradually being organized into an integrated whole, with long-term applications to many Soviet programs outside the realm of medicine, particularly in the vast panorama of aerospace operations.

### Prosthetics Facilities

For a fuller review of Soviet surgical and prosthetics facilities, the reader is referred to a previous report (4), which presents in detail the organization, administration, and functions of experimental and clinical surgical practice in the Soviet Union today. The following information is designed to orient the reader in the area of prosthetics facilities.

The growth of institutes and other facilities for surgical research and clinical practice in the Soviet union has grown almost unceasingly since 1946. The Institute of Surgery imeni A V Vishnevskiy, the oldest and one of the outstanding surgical facilities in Russia--indeed, in the world--was founded some 20 years ago, and is presently under the directorship of the founder's son. It includes five clinical sections and numerous laboratories, among the latter being one for biocybernetics research and development, created in 1960. Professor Vishnevskiy and his colleagues and staff members have contributed substantially to Soviet developments in various areas of prosthetics, as evidenced in the main sections of this report. A perusal of the Table of Contents of this paper gives some indication of the wide scope of prosthetics, in terms of types of materials, of organs and tissues, and of prostheses. It is not surprising, therefore, that the scope of Soviet surgical facilities involved in such research should reflect this broad span of interest and activity.

The outstanding facility for cardiovascular prostheses in Russia is the Institute of Cardiovascular Surgery in the Academy of Medical Sciences of the USSR.

The following list presents some of the other major facilities concerned with prostheses and prosthetics in the Soviet Union.

Academy of Medical Sciences--President, N N Blokhin

Department of Clinical Medicine--Academician-Secretary,  
V Kh Vasilenko

All-Union Scientific Research Institute of Medical Instruments and Equipment--Director, I P Smirnov (?)

Academy of Sciences--President, M V Keldysh

Military Medical Order of Lenin Academy imeni S M Kirov

Chair of Traumatology and Orthopedics--Head, I L Krupko

Chair of Hospital Surgery--Head, G S Yumashov

Ministry of Health of the USSR--Minister, V M Zhdanov

Central Scientific Research Institute of Prosthetics and  
Orthopedic Appliances--Director, B Popov

Central Institute of Traumatology and Orthopedics--Director,  
M V Volkov (institute now under the Academy of Medical  
Sciences)

Department of Orthopedics of Children

Department of Orthopedics of Adults

Department of Traumatology

Laboratory of Plastics

Scientific Research Institute of Experimental Surgical  
Apparatus and Instruments--Director, M G Ananyev

Ministry of Public Health of the RSFSR

Scientific Research Institute of Orthopedics and Restorative  
Surgery--Director, U Ya Bogdanovich

Chair of Traumatology and Orthopedics--Head, L I Shulutko

Scientific Research Institute of Orthopedics and Traumatology,  
Donetsk--Director, T A Revenko

Scientific Research Institute of Restorative Surgery, Traum-  
atology, and Orthopedics, Minsk

Scientific Research Institute of Orthopedics and Restorative  
Surgery, Saratov--Director, Ya N Rodin

Scientific Research Institute of Orthopedics and Traumatology,  
Tashkent--Director, B Akhundzhanov

Scientific Research Institute of Restorative Surgery, Traumatology, and Orthopedics, Gorkiy--Director, M G Grigoryev

Scientific Research Institute of Traumatology and Orthopedics,  
Riga--Director, V K Kalnberz

Scientific Research Institute of Traumatology and Orthopedics,  
Baku

Scientific Research Institute of Traumatology and Orthopedics,  
Kiev--Director, I Aleksayenko

Scientific Research Institute of Traumatology and Orthopedics,  
Kazan

Scientific Research Institute of Orthopedics and Traumatology,  
Irkutsk--Director, Z V Bazilevskaya

Department of Traumatology

Scientific Research Institute of Traumatology and Orthopedics,  
Sverdlovsk--Director, Z P Lubegina

Scientific Research Institute of Traumatology and Orthopedics,  
Novosibirsk--Director, D P Metelkin

Scientific Research Institute of Experimental and Clinical  
Surgery, Tbilisi

Scientific Research Institute of Traumatology and Orthopedics  
imeni Vreden, Leningrad--Director, V S Balakhina

Ukrainian Institute of Tuberculosis and Chest Surgery

Thoracic Surgery Clinic

Scientific Research Institute of Experimental Surgical Equipment and Instruments, Ministry of Social Security, RSFSR

Leningrad Institute for the Advanced Training of Physicians  
imeni S M Kirov



## PROSTHETICS

General

One of the main avenues of the Soviets' approach to solution of problems in medicine, surgery, and allied sciences is the identification of pathology in terms of disturbances in one or more physiologic control systems. Their approach to medical research and practice, therefore, is one of identifying such control mechanisms and re-establishing normal equilibria. In pursuit of this objective, they have relied heavily on biochemical and biophysical research, ostensibly to a much greater degree than we in the United States. They have further sought to strengthen this line of research with the development and evaluation of biologic models of both normal and pathologic functions. Thus, they have developed a so-called "dynamic" heart model, consisting of an electronic module connected to a dipole which reproduces cardiac bioelectric activity. The model, inside a simulated torso, permits one to study the dynamics of surface potentials during changes in the electric circuit characterization of the dipole, in the torso shape, and in the electric circuit conductivity. Such developments are outside the realm of prosthetics; however, they serve a dual purpose. They stimulate research in the duplication of the functions of parts and organs, which is bionics; and they supply models for the study of many physiologic and pathologic conditions.

Major developments in Soviet prosthetics research are based on consideration of each prosthesis as either a bionic unit which responds to external control from other parts of the body, or as a biocybernetic device which itself controls one or more vital functions and other parts. Soviet prosthetics research is currently being oriented toward maximum application of cybernetic developments from other areas, particularly research in biologic modeling and analysis of physiologic control mechanisms. There is also a strong effort to integrate more closely the results of biochemical and biophysical investigations with developments in cybernetic, automation, and systems control theory.

The scope of reconstructive and restorative surgery is broad and encompasses as its targets every tissue, organ, system, and part of the human body. Thus, it is possible to visualize artificial skin, muscles, bone, heart, kidneys, lungs, blood vessels, glands, arms, fingers, legs--in fact, any and all parts. Some of these goals have

already been realized, either totally or partially. Others seem to be on the threshold of discovery. Still others appear to our present state of knowledge and technology quite impossible.

Every body cell has a function, frequently many small functions, which may or may not be related to one another and which together perform another overall function. As cells aggregate to form tissues, tissues to form organs, and organs to form systems and parts, these overall functions become increasingly intricate and complex, and hence generally more difficult to replace. But this is not always the rule. Simple tissues may have functions equally as complex as those of highly structured and systematized organs, as the heart, liver, and spleen.

One can divide the area of prosthetics into two broad categories; temporary and permanent. Temporary prostheses are applicable to organs and parts which are capable of ultimate regeneration, replacement, substitution, or natural repair. In this one relies on the innate vital capabilities and forces of the body. "Nature cures its own" and "leave it alone and it will heal"--are only two of innumerable aphorisms handed down by generations of lay and medical people alike. Unfortunately, while many tissues can regenerate or repair their own structures and functions, this may take more time than the rest of the body, which relies on the functions of the injured part, can afford. Thus, the organism may die during such an attempt. In such cases nature needs temporary assistance to supply the vital support or function while the organism restores or repairs the needed part. Examples of this include many of the large and medium-size blood vessels, the parietal membranes and tissues, and parts of the digestive system. The fact is immediately clear that such parts play essentially passive or structurally supportive roles. One might also include a covering of collodion or other protective material over a debrided area of skin, which serves to restore some of the functions of the skin--e.g., protection against fluid loss and microbial invasion, until the skin in the area can be regenerated. This is also a temporary prosthesis.

Permanent prostheses are usually required to replace active or metabolic functions. Examples include circulation of fluids, oxygenation of fluids and tissues, filtration or dialysis, and locomotion or movement. In some cases nature has generously provided pairs of organs, with large margins of functional capacity, as in the kidneys. In others it has provided a single organ with an even greater margin of capacity, as in the case of the liver, spleen, pancreas, and heart.



In still other instances, as for example the extremities and their parts, a lost or permanently injured part cannot be regenerated in its entirety. Nor can its function be replaced by the remaining (if any) corresponding limb, although some compensation may be possible. Again, the activity, physical condition, and other factors controlling the health of the individual may be such that one part becomes badly worn and is rapidly approaching the limits of its marginal capacity or beyond. Such parts also require permanent replacement.

Lastly, there are a group of organs and tissues which are at present beyond our knowledge and technology to replace, restore, or temporize during regeneration. One cannot generalize as to their type of function or activity. On the one hand, there are the large group of "chemical factories" which manufacture and destroy literally thousands of biochemical substances continually; these organs include the endocrine glands, liver, spleen, bone marrow, and many others. In some cases the functions of these organs can be taken over by other divisions of the cellular system in other parts of the body, as in the case of bone marrow, lymphoid tissue, and the reticuloendothelial system, all of which are widespread throughout the body. In other instances--e.g., the endocrine glands, nonprosthetic restoration of "function" can be accomplished by the implantation, for example, of pellets containing the necessary chemical products of these "factories"--viz., hormones. But always one comes to a technologic impasse--a gap or lack in our present knowledge which permits us to proceed no further, as in former days we could not proceed even to our present state of achievement.

The remainder of this section will be devoted to two broad areas: the materials currently being used in the construction and manufacture of prostheses, and the prostheses themselves. The latter are divided, for purposes of this report, into two classes; on the one hand are those prostheses which are constructed of relatively simple materials, are of relatively simple design, and perform comparatively uncomplicated functions. On the other hand are those prostheses which are more complex in design, construction, and function. The first group is discussed under the general head of Alloplasty, or reconstructive surgery, and the second under the heading of Prosthesis, or restorative surgery.

## ALLOPLASTY

Materials

The discussion of the materials used in the construction of Soviet prostheses is herein limited to plastic, polymeric materials. It is included under Alloplasty because the largest portion of these materials are used in the production and fabrication of alloplastic prostheses. Moreover, the special properties of certain plastic polymers have made them particularly suitable and adaptable to alloplasty. In effect, it is doubtful that progress in this area could have been made without the developments and continued research in synthetic polymers. Replacement prostheses, on the one hand, are constructed largely of light metals, metal alloys, specially treated and prepared woods, plus electronic and mechanical components; many of the softer parts of such prostheses, such as coverings, joint hinges, and the like, may be made of plastics, but the required properties of such materials which form the basis for their selection are quite different from those for the selection of intracorporeal devices. There are, of course, exceptions, and in the next section these include the restorative intracorporeal prostheses.

Materials used for extracorporeal devices require only those properties which allow the components which they comprise to perform the functions that are being restored. There is no interaction among these components and materials with biologic materials, except at the points of connection, if any, to the subject, and insofar as certain body fluids perfuse these apparatuses. When the prosthesis is intracorporeal, however, the interactions between the materials and living tissue become of prime importance in deciding what, how, where, and when to use these substances. The body tissues and fluids have a greater or lesser tendency to react to foreign--i.e., nonbiologic, materials in many ways, ranging from a simple irritation to the violent rejection of the foreign material. Moreover, even after the foreign body has been removed or rejected, the initial reaction between it and the tissues may continue for some time. One of the greatest dangers is neoplastic reaction, specifically, carcinogenesis. Numerous plastics have been observed to cause such reactions in the tissues of small laboratory animals and occasionally in those of humans. Further developments in prostheses using these plastics has generally ceased. Carcinogenic reactions of this type have usually been observed to be time-dependent.



All reactions of plastic materials with body tissues and fluids depend on the chemical class and reactivity of the particular substance. A broad spectrum of synthetic polymers is now available, both in this country and abroad, and the list is growing daily. Their physical, chemical, and biologic properties span a wide range. Some are prepared in sheets as thin as 0.01 mm or less, while others can be molded in large forms. Some can be prepared as fibers of varying lengths and thicknesses and then made into threads which can be woven in cloths of various meshes. Still others can be formed in continuous filaments for subsequent processing into cloth. Other types can be prepared as felts from fibers of various sizes and properties.

Among the physical properties of plastics which are of interest and importance to the surgeon are elasticity, tensile strength, tendency to cold flow, specific gravity, specific volume, and hardness. Also of interest are its thermal properties--viz., heat distortion, softening point, and thermal conductivity, as well as its dielectric strength. The working properties are also important, that is, the forms of the material which are available, and the physical properties peculiar to those forms. Of very great importance in relation to their biologic use is the porosity, and since this is frequently related to the form--e.g., film, sheet, plate, or block, the latter must also be considered.

The chemical properties of plastics used for intracorporeal prostheses and for those parts of extracorporeal devices which come into contact with biologic tissues and fluids are related most closely to their reactions with biologic systems. One is not especially worried that a plastic softens at 50 °C, or that it swells in strong alkaline or acid solution, or dissolved in various organic solvents which would never come in contact with it in the body. Of great concern, however, is the action of water at body temperature, and especially of the enzymes which are found in all tissues and fluids, of the solvating properties of body lipids, and the like. Of equal importance is the effect of the polymeric material itself, as a chemical class, on various substances and systems in the body. The latter also includes certain toxic effects which have been noted in connection with the use of some materials.

The effects of prosthetic materials on various aspects of cell growth is also due much consideration. Thus, one is interested in effects on rate of cell growth, mutagenic effects, types and quantities

of tissue growth stimulation or inhibition, abnormal effects on sub-cellular structures and organization, and the possibility of carcinogenesis. It has been found that most of these reactions--physical, chemical, and biologic--depend upon the time of contact of the material with the tissue. In surgical and medical practice it has frequently become necessary to equate the advantages and disadvantages of a particular type of prosthesis, and to balance the restorative effects against the deleterious ones.

Thus, one has potentially available a very broad range of materials with which to repair, restore, or replace the equally broad, if not broader spectrum of body tissues and functions. With regard to plastic materials, these range from fine mesh, porous, semisoluble products, such as capron, ivalon, and vinyon, to solid, monolithic, and extremely inert ones, such as polyethylene and teflon.

Soviet philosophy in the development and application of this wide range of available materials has been based, apparently to a greater extent than in the United States, on the systematic correlation of physical, chemical, and biologic reactivities to the requirements of the tissues which they are designed to replace. Russian materialistic concepts being what they are, it is not surprising that the Soviets consider the manufacture of artificial polymers analogous in structure, and hence function, to natural one, that is, proteins, a "fully realizable task." While this may be true for certain simple polymers and copolymers, such as polysaccharides, as pointed out by Rich in the United States in 1961, one finds it difficult to conceive of the mass or even pilot production of polymers containing more than one or two simple residues. Be that as it may, the Soviet view of the success of polymeric prostheses is just that they are polymeric; in other words, they resemble or reproduce "natural" substances and structures. The search for various polymeric substances for use in a wide range of prosthetic devices goes on, according to the particular needs of the tissue involved. Thus, one may require rigidity or flexibility or any point between these extremes. Porosity may be needed in varying degree, from a large mesh to a relatively nonporous monolith. Both in this country and abroad, surgeons, physicians, and other members of the prosthetics team are aware that the ideally suited material for all types of prostheses has not been found. Nor is it likely that a single material can or need be found. In some instances the biologic reactivity of the material, particularly on a long-term basis, is either not sufficiently well defined or known. The reactions of a synthetic



polymer to heat, cold, steam, desiccation, flexing, pressure, and so forth may be immaterial in the face of oxidative, proteolytic, and other enzymatic processes, cellular infiltration, and other biologic activities which occur in the tissues at the site of the prosthesis.

While one can compare natural and artificial polymers with respect to structure, form, and physical and chemical properties, one fundamental difference remains--artificial polymers are in no instance regenerative. This fact is interesting and provocative in the face of the Soviets' hypothesis of natural vs artificial polymers. Moreover, while one can temporarily replace a structure or restore a function, one is hard put to replace or restore the viability of the part and, more particularly, the complex interrelationships of function and activity between the restored part and those surrounding it. This view has frequently necessitated consideration of prosthetic design in terms of these relationships, as well as of the required function itself. Many excellent results have been obtained on a short-term basis, but frequently the long-term results have been disappointing.

There is little indication that the Soviets are making any effort to manufacture the basic polymeric materials in their own country. They doubtless feel that it is considerably less expensive to buy what they need abroad and process it in their own ways, rather than build expensive manufacturing plants for each of the various plastics. Most of the Soviet literature in this area uses trade names of plastics which originated in various countries of Western Europe, as well as of some from the United States. The following table lists the common plastic materials now being used in Russia in the fabrication of alloplastic devices.

The biologic reactivity of alloplastic materials is determined by biologic tests, and is frequently a function, among other things, of the particular tissue and the form and type of prosthesis. Most of the information in this area will be given in association with the discussion of investigations on the various tissues, organs, and parts being restored. The remainder of this section is limited to general remarks on reactivity and usefulness of plastics in this area.

Goldina and Kadin (5) reviewed a selection of plastic materials for prosthesis, with special reference to repair of defects of the dura mater. Most of them (cellophane, polyethylene, orlon, vinyon N, and polyvinyl formalin sponge (Ivalon)) have only been used experimentally

Table 1

## Russian and American Trade Names for Prosthetic Materials

Russian Name	American Equivalent	Other Trade Names	Chemical Class
Fluorlon Fluoroplast-4	Teflon	Fluon, Fluoroflex	polytetrafluoro ethylene
Ftorlon	Kel-F (?)	---	Tetrafluoroethylene + vinylidene fluoride
Polyethylene	polyethylene	Polythene, Alkathene Agilene	Polyethylene
Perlon	nylon 6	---	polycaprolactam
Capron	nylon	Silon, Furon, Kapron	polyalkylamide
Terylene Lavsan	Dacron	Diolen	terephthalic acid + ethylene glycol
Orlon	Orlon	---	polyacrylonitrile
Vinyon N	---	PVA, Polyviol, Vinarol, Vinol	acrylonitrile + vinyl chloride
Ivalon	Ivalon	---	polyvinyl formalin
Porolon	---	---	polyurethane

in the Soviet Union. In their studies of 6 plastic materials, the authors observed moderately extensive inflammatory reactions, with formation of connective tissue around the implant in all cases. Thinner capsules were observed around filmy, porous materials than around less porous substances. The former (polyethylene, teflon) were preferred.

The use of polymers for alloplasty in Russia began with plastic repairs of cranial defects (6). Thereafter, a Plastics Laboratory was established



at the Central Institute of Traumatology and Orthopedics. The first plastic developed in this laboratory was used for reconstructive maxillo-facial surgery. Following developments for large-scale production of methyl methacrylate polymers, Soviet surgeons were at last able to perform such operations as replacement of cranial defects, arthroplasty of hip and knee joints, and others. These developments in rigid supportive plastics were followed in the early 1950's by soft plastics for tissue repair. Soviet surgeons in 1952 were able to reinforce a double abdominal hernia repair with perforated plates of teflon, and later (1953-1958) with capron mesh. Similar reinforcements of the diaphragm using ivalon mesh were accomplished in 1957.

Bykova and Dobrova (7) conducted three series of experiments with dogs, using 10-cm lengths of vascular prostheses prepared from various plastics. These were sutured into the descending aorta with the Soviet automatic vascular suturing apparatus. The first group consisted of nylon and capron prostheses, the second of dacron and lavsan (terylene), and the third of teflon, ftorlon, and dacron-teflon, for a total of 61 cases. A fourth group of 30 cases involved the use of polyvinyl formalin (ivalon) prostheses. Their results, which did not differ significantly from those of American workers (8-12), indicated that capsule formation, thrombosis, and fibrin formation occurred regardless of the plastic used. However, the rate of formation of reaction increased with the chemical reactivity of the polymer. In this series capron, dacron, and lavsan seemed to be the most reactive, while teflon-dacron, teflon, and ftorlon were least reactive. Thrombosis occurred most readily with capron and ivalon, and least readily with teflon and ftorlon.

Shelyakovskiy (13) in 1955 observed that such plastics as polyvinyl butyral, polymethacrylate, and polyamide change their physicochemical properties in vivo and dissolve or disintegrate in animal tissues and fluids. Polyethylene and teflon, on the other hand, were both chemically inert, although the former frequently did not have sufficient tensile strength to be used as a graft. Teflon induced strong capsule formation and was not infiltrated with connective tissue when used in the monolithic form.

Soviet surgeons were using capron as early as 1961 (14, 15). They described it as a chemically and biologically inert, very durable, non-hygroscopic, and almost nonwetttable substance, which we now recognize as being a polymer very similar in structure and composition to nylon. In the form of cloth it was extremely versatile, being easily shaped and cut. Its porosity permitted the passage of cellular elements.

Capron gauze implants of various meshes and ranging in size from 18 to 1,200 sq cm were used in hernioplasty (16), with no relapses after 36 months. Capron mesh is now being used extensively in the Soviet Union for the repair of abdominal organs, pleural cavity membranes, and the diaphragm, and in cases of rectal and uterine prolapse. In fact, several of the porous, semisoluble plastics have been and are being used in a wide variety of surgical repairs. The fact that a material is porous and semisoluble does not preclude its use. In many cases of surgical repair and restoration, the function of the prosthesis need be only temporary. It may be required only so long as the injured or otherwise defective organ or part is in the process of regeneration or replacement. In cases of tissues and organs which cannot be entirely or at all regenerated--viz., liver, kidney, lung, heart, nerve and so forth, a true permanent prosthesis is necessary. Capron is not affected by boiling and it does not dissolve in alcohols, ethers, fats, or organic solvents. Capron fabric used to replace a section of diaphragm (17) was slowly disintegrated and absorbed within a year.

Ivalon and capron were among the first polymers used by Soviet surgeons for vascular prostheses. Soviet industry now manufactures knitted, woven, and plaited vascular prostheses of these and other synthetic fibers, such as lavsan and fluorlon. Soviet tests on the latter two substances have shown that tissue fluids have no action on them after periods up to 2 years. Capron, on the other hand, loses about 40% of its rigidity within 15 days in vivo, and disintegrates almost entirely within a year. Where rigidity is required, as in orthopedic procedures, the polyacrylics were disappointing, as were prostheses manufactured of ivalon. Acrylic plastics were used for fixation of the spinal column, however, these prostheses tend to deform and were found to be generally unsatisfactory for this purpose. A capron prosthesis for primary replacement of the shoulder has been used in 35 humans with fair to good results.

Lipovetskiy reported the use of polyvinyl sponge (ivalon), capron, polyethylene, and combined plastics for the experimental replacement of bile ducts. Pokrovskiy and Kreyndlin (18) reported the successful use of perforated polyvinyl chloride plates 1 mm thick for hernioplasty and diaphragm repair. There was some indication of absorption after 1 year.

Porolon, a soft polyurethane foam, was proposed for surgical use in Russia in 1957 (19). It has since been used by Soviet surgeons for



plombage of the pleural cavity and more recently for repair of the anterior abdominal wall. Porolon is strong enough for this purpose, and is sufficiently elastic that it does not interfere with muscular contraction. As it is used in the Soviet Union, porolon has a fine mesh which becomes infiltrated with fibrillar connective tissue within 20 to 30 days.

Kovalenko (20) in 1962 considered that lavsan had no deleterious effect on cell growth, based on the absence of malignant cells in the surrounding tissues. Further histologic examination revealed no abnormality of cellular growth. Lavsan was used successfully in 125 cases of rectal prolapse, 70 cases of extensive hernia, and 50 cases of dislocated kidney. The latter were supported by lavsan "hammocks" attached to the 11th rib.

The Soviets have used microscopic visualization of the microstructure of the walls of prostheses, particularly for blood vessels, to test their quality (20a). They claim to be able to change the microstructure by further chemical processing--i.e., after manufacture. Marulin (21) proposed the inclusion of soluble fibers (polyvinyl alcohol or sodium alginate) in various prostheses. Swelling of such fibers strengthened the walls and prevented leakage of blood. Resorption of the fibers promoted more rapid development of granulation tissue. This had previously been recommended by Gubanov (22) in 1961.

According to Degtyareva and Lavushcheva (23), catgut is still widely used for suturing tendons in the Soviet Union; silk is seldom used. Capron has been found highly desirable as a suture material because of its durability, smooth surface, and ease of sterilization. As noted elsewhere (17), there has been some evidence of its resorption in human and other animal tissues. Using tantalum or stainless steel wires in rabbits, these authors observed granulation and connective tissue formation and fibroblastic activity around the wire sutures within 7 to 45 days. Similar results were observed with capron thread, as well as an inflammatory reaction within 30 days. For the latter reason, the authors preferred wire to capron for this particular procedure.

Vishnevskiy (6) has noted the observations of American workers in 1952-1955, confirmed by others in both countries, of the carcinogenic properties of cellophane, polyvinyl chloride, polyethylene, dacron, and many other plastic materials. This reactivity, according to Russian evaluation, seems to be closely related to the size and form of the plastic, as well as to the time of contact with living tissues. The greater



the surface area of the prosthesis that is exposed to the tissues, the less will be the carcinogenic reactivity. Since, however, all such observations have been made in mice and have never been confirmed or observed in other animals, including humans, there has been no rational basis for discontinuing research in alloplastic materials and prostheses.

### Esophagus

Esophageal alloplasty was performed in the United States as early as 1922 (24), using rubber tubes. The latter stimulated the formation of epithelial granulation tissue which eventually replaced the defect. The reaction was subsequently observed to be practically independent of the material used (tantalum mesh, polyethylene, ivalon, nylon), and was in fact considered necessary for complete functional restoration. Removal of esophageal prostheses prior to complete epithelialization and encapsulation of the prosthesis frequently led to esophageal stenosis, cachexia, and death. Kulik (25) studied the optimum conditions necessary for successful esophageal alloplasty in dogs, using ivalon, polyethylene and teflon to replace 3 to 7-cm circular resections. Histologic examinations showed that tight sealing of the granulation tissue around polyethylene and teflon was complete by the 15th to 20th day. A tight seal could not be obtained around ivalon even after 30 days, because of its porosity. Hemogeneity of the capsule around teflon and polyethylene was observed by the 30th day. Between 1 and 12 months new blood vessels, smaller than normal, were found in the newly formed capsule. Stenosis (reduction of luminal diameter by 50% or more) was observed quite frequently. The cause of this could not be determined.

Following the work of the American surgeon Berman (26), Kharitov et al. (27) replaced the esophagus of dogs with nonperistaltic plastic tubes, using three methods of attachment. Only that in which the tube was inserted into the lumina of the resected ends of the esophagus was at all satisfactory. In some dogs in which the tubes were in place for over a year and then migrated to the stomach, some peristaltic activity was observed in the newly formed tissue. Removal of the prosthesis earlier than one year led to scarring and constriction.

### Ureters

Working with dogs, Fedorov (28, 29) removed the ureters, leaving 2 to 3-cm upper and lower stumps. He then inserted 15 to 17-cm lengths of polyethylene tubing. Within 6 to 7 months the upper stump elongated

and dilated, due to increased peristaltic activity. Roentgenologic examinations, according to Derevyanko (29), indicated no regeneration of ureteral tissue. Fedorov, on the other hand, claimed that regenerative capacities were present, although they had not been used because of the permanent prosthesis.

### Blood Vessels

Petrovskiy (30) has cited the potential dangers of aneurysm or rupture of blood vessels when using lyophilized dead homografts, because of degeneration of the intimal layers of the grafts. He noted the work of Kovanov, Filatov, Sitenko, Bakalev, Ananyev, and others in the development and use of prostheses woven of plastic threads. These porous tubes permit initial blood flow through their walls but shortly become impenetrable due to fibrin formation in the interstices. Advantages of these tubes are their role as supportive networks for new tissue formation and the fact that the inside surface eventually becomes endothelialized. Their disadvantages, according to Russian surgeons, are eventual scarrification, cirrhosis, and thrombosis; in the case of the latter the entire prosthesis may act as a "foreign" body, producing inflammation and ultimate separation and rejection. The Soviets have suggested that such prosthesis be made of both stable and semisoluble fibers. Soviet surgeons have pointed out--quite rightly--that in using plastic prostheses for the replacement of occluded arteries one literally burns one's bridges behind one, through the ligation of collateral arteries. Plastics are therefore recommended only for prosthesis of the aorta and the large arteries and veins. The Soviets appear to have had extensive experience with plastic prostheses in a wide variety of vascular surgical problems, one clinic alone having performed some 600 major surgical operations on blood vessels during the past 10 years; the number of plastic prostheses used, as compared with autografts and homografts, was not stated.

As late as 1963, alloplasty of blood vessels smaller than 7 to 10 mm in diameter was generally unsuccessful throughout the world. American experiments with femoral artery grafts of 4 mm in diameter were almost entirely unsuccessful (31). Cate (32) reported, on the other hand, 90 to 100% success with arterial and venous autografts, and only 40% with dacron prostheses in the femoral area. The Soviets (33) have obtained generally unsatisfactory results with vascular alloplasty in the femoral-popliteal region because of thrombotic occlusion in tubing of such small diameters. Podlaga et al. (34) have noted the unsuitability of plastic



prostheses for small-diameter vessels. All of 24 terylene prostheses used in the aortic-femoral-popliteal region in dogs terminated in thrombosis.

In 1962, Anichkov and Balyuzek (35) described rather cursorily their experience with a wide range of vascular prostheses in dogs. Much of this work was undertaken in order to eliminate or reduce the contradictory problem of "preclotting" of prostheses, according to DeBakey (36), against the background of artificial hemophilia necessitated by the surgical requirements of the procedures. Thus, allografts ranging from rigid monoliths to woven and corrugated meshes were subjected to preliminary treatment with a variety of solutions to saturate the prostheses. The solutions contained chiefly fibrinolytic enzymes, antibiotics, and a source of protein, either gelatin, chicken plasma, or human fibrinogen. Alternately, the prosthesis was bathed in the recipient's own blood until it was saturated with fibrin. The authors described their results as "encouraging."

Berezov et al. (37) used allotransplants of dacron, teflon, and terylene for the replacement of the inferior vena cava in dogs. In all cases where the graft was higher than 3 cm below the entry point of the renal veins, thrombosis occurred within 1 to 4 months. A high percentage of thrombosis was observed (38) with the use of capron prostheses of the abdominal aorta in dogs. Best results were obtained with elastic dacron prostheses. Pismenov (39), on the other hand, observed obliteration and thrombosis of the vena cava using capron net and polyethylene. He obtained best results with woven, corrugated terylene (dacron). Terylene prostheses are manufactured on a large scale in Czechoslovakia (34). Fedorovskiy (40) obtained equally good results with woven dacron prostheses in canine arteries 6 to 8 mm in diameter. Kovalenko (41) also obtained good results in rats, using dacron to strengthen tissues and immobilize organs. In his description of the preparation of corrugated capron tubing, Ivanov (42) pointed out that corrugation "somehow" increased the elasticity, flexibility, and pulse-propagating abilities of vascular prostheses.

Galperin (22) used corrugated prostheses of lavsan-capron to replace resected abdominal aortas in a series of 20 dogs. No thrombosis occurred 9 months after surgery. Pipia and Telia of Tbilisi (22) found dacron to be the best material for prosthesis of large vessels. Capron and nylon were almost as satisfactory, while polyvinyl alcohol was considered to be less durable and reliable for replacement of the aorta. Kurygin and Smirnov (43) used lavsan prostheses in dogs for replacement



of carotid artery segments, with capron thread sutures. Lavsan is porous and the mesh is shortly filled with fibrin. Connective tissue formation occurs on this base, with subsequent resorption of the fibrin. Endothelialization, with new vessel formation, required 3 to 7 months or more. The authors also observed that protracted endothelialization resulted in obstructive thrombosis in almost 40% of their cases. They related the time for new vessel formation to, among other things, the length of the prosthesis. If this is correct, it implies that new vessel formation proceeds from one layer to another, each being laid down before the next one above it, rather than all layers being regenerated concurrently. Kurygin (44) was able to examine histologically a series of 16 lavsan prostheses removed from patients for various reasons 5 days to 19 months after surgical implantation. Six aorto-femoral shunts were still patent, and were removed at autopsy. One iliac-femoral shunt was removed during a repeated restoration due to thrombosis. Of 5 femoral-popliteal grafts, all had become thrombotic, as had all of 3 iliac-popliteal prostheses. One of the former and all of the latter necessitated amputation. One brachial graft in the axillary region was patent, and was removed at autopsy. Inflammatory reactions around the prostheses reached a maximum by the 7th to 9th day. Endothelialization reached an extent of 3.5 to 4 cm during 8 months; this appears to have been independent of the overall length of the prosthesis. The author noted that tissues surrounding a vascular prosthesis reacted in different ways under conditions of patency and obliteration.

Filatov et al. (45) described their experience with ivalon and other plastic prostheses in 1962. They established 18 requirements, divided into five groups. These concerned (a) the effects of the prosthesis on the patient; (b) the mechanical properties of the prosthesis; (c) the functional properties of the prosthesis; (d) the surgical requirements; and (e) the external characteristics of the prosthesis. The authors used knitted corrugated prostheses in 24 patients, of whom only one died. The prostheses were used between the (a) aorta and femoral artery; (b) iliac and popliteal arteries; (c) iliac and femoral arteries; (d) femoral and popliteal arteries; and (e) upper and lower thirds of the femoral artery. The nature of the prosthesis used in the patient who died was not stated nor, unfortunately, was the plastic used for the entire series. The description, however, seems to indicate that it was ivalon mesh reinforced with nylon.

From the extracts of Soviet literature discussed above, the plastics currently being used in that country for alloplastic prostheses can be

placed in the following approximate order of increasing biologic reactivity: ftorlon, fluorlon, and fluoroplast; polyethylene; perlon, capron, and lavsan; terylene, orlon, and prolon; vinyon; and ivalon. In this order, they are increasingly useful for the restoration of defects which will eventually replace themselves or become covered or infiltrated with scarring, connective, or fibrous tissue. Conversely, their order indicates decreasing usefulness when a permanent, long-term prosthesis is required. Generalizations as to particular applications of these materials to particular tissues seem inappropriate, because the size, shape, and location of the defect, and also the size, form, and type of allograft, as well as its biologic reactivity, all enter into consideration here.

## PROSTHESIS

Larynx

There is surprizingly and disappointingly little information on artificial vocal apparatus development from the Soviet Union. In 1963, the Committee on New Medical Equipment of the Ministry of Health, USSR, approved three designs for serial production. All had a sound generator to produce frequencies from 110 to 250 cycles per second; one of them used an electronic audio oscillator, while the others used an electromechanical unit of the buzzer type. A more sophisticated model was designed and produced by the Kiev Medical Apparatus Plant. This electronic unit used the principle of the "speaker's" own throat and other sound-forming passages to operate a transducer contained in a flexible tube which was held in the subject's mouth (46).

On the other hand, the Soviets have a strong research program in elucidating the biophysical parameters and mechanisms of speech and sound formation (47). They lay much stress on biocurrent patterns from the various muscle groups which contribute to sound production (see under Biostimulation). They have recorded, among others, rates of air movement from the mouth and nostrils, lip and lower jaw movements, vibrations of the vocal folds, and acoustic patterns within the nasal cavities and of normal speech. Integration of these data would have a distinct potential toward the development of improved artificial vocal apparatuses for prosthetic purposes, perhaps even one operated through the use of biocurrents.

Ear

Another interesting application of biophysical research, with potential for prosthetic development, is being investigated by Chinese physiologists (48). Research is being conducted in the field of electro-auditory stimulation, which was originally noted by Ford in the last century. Ford observed that the application of an electric stimulus to the ear produced the sensation of a feebly audible sound. This work was continued by the Soviets in the 1930's, when they observed that stimulation of the auditory organ (nerve?) resulted in subjective perception of tones of frequencies comparable to those used for stimulation. This response was elicited even after the stapes was removed. The recent Chinese investigations showed that passage of an electric impulse through one individual by means of a thin silver-plated elec-



trode of large area could cause a sound at the skin-electrode interface which was audible to another person close by. The Chinese assert that the mechanisms of electric stimulation and mechanical vibration are not mutually exclusive, but rather complement each other. Refinements in methodology and equipment could lead to the development of a bioelectrically controlled prosthetic auditory device. This could contribute greatly to the retraining of deaf persons, in terms of their own voice sounds and intensities.

### Nerves

Soviet reports on prosthetic nerve developments are equally sparse, but there certainly appears to be a considerable amount of effort being spent in this direction. In 1961, several popular reports (49, 50) appeared of the replacement of the sciatic nerve in dogs with an "arc-like metallic electrode." Medical and surgical observers were able only with some difficulty to identify the limb which had undergone the operation. These reports also claimed that a vagal nerve prosthesis had been successfully implanted in one dog for 9 months, and a laryngeal nerve prosthesis in another. There were also reports on the development of an optic nerve prosthesis, as well as those for other spinal nerves; the former use wires which are invisible to the naked eye. It is evident from this and other reports (51) that numerous experiments are being conducted by Soviet physiologists and surgeons on the replacement of various nerves through the apparently simple expedient of substituting them with very fine tantalum or platinum wires.

In this same area, the Soviets are engaged in the development of a visual prosthesis, by means of which the blind can read printed material (47). The current prototype is being designed to convert printed letters and words into Braille; the long-term goal is to convert them into sounds or sound codes.

### Artificial Kidney

Lest there should be any question in our minds, the technique of hemodialysis was first applied to the removal of diffusible substances from the blood of living animals in 1913 by Abel and others in the United States (52). The original device consisted of a single continuous length of collodion tubing enclosed in a glass cylinder containing Ringer's solution. The two ends of the tubing were attached to the ends of a severed artery. While stark in its simplicity, this device provided the main attributes of the artificial kidney of today--diffusion against a concentrated gradient, sterility, and exclusion of air.

The Soviets appear to have entered the artificial kidney field, with respect to its clinical application, only some time in 1963 (53,54). Since that time the apparatus has been widely used in the Soviet Union and its satellites for the application of various renal and other conditions. By the end of 1963, seven special centers in the Soviet Union were using artificial kidney equipment in practice on human subjects. The apparatus in use at that time was equipped with an ultrafilter and a dialyzing unit with approximately 15,000 sq cm of surface area (54a).

Typical Soviet techniques using the artificial kidney apparatus with dogs in 1962 are described below (54b). Blood was collected from the inferior vena cava and returned to the superior vena cava through the external jugular vein. Coagulation was inhibited by the administration of 4 mg of heparin per kg. The following tests were conducted: arterial pressure, ECG, respiration and pulse rates, and temperature; blood hemoglobin (Hgb), plasma Hgb, viscosity, specific gravity, erythrocyte osmotic fragility, morphology, etc.: components of the coagulation system, particularly coagulation time and prothrombin time (Quick); and biochemical data, including urea, K, Na, Cl, total protein, pH, and others. Histologic examinations on sacrificed dogs revealed no changes which could be related to hemodialysis. A number of technical errors were reported, including improper preparation of the dialyzing solution and "bleeding" into the apparatus. Both of these resulted in deaths. Deaths due to arterial pressure drop were attributed to toxic factors associated with Soviet cellophane membranes.

Experiments with uremic (bilaterally nephrectomized) dogs gave generally poor results in the hands of Soviet surgical teams at that time (1962). Urea was reduced by only 30% from initial values of about 275 mg% (figures almost illegible), and all of the dogs died within 3 to 7 days. The authors were reluctant to admit that their failures might have been due to improper servicing and handling of the apparatus, and rationalized the poor results on the basis of (a) development of the uremic condition, (b) increased species sensitivity of dogs to hemodialysis due to (a), (c) "chemotransfusion reactions the cause of which remains for the present insufficiently clarified."

The following technical data were available for the apparatus described above (55). The dialyzer was filled with 42 liters of 500 mg% urea solution. The dialyzing solution consisted of 120 liters of distilled water circulated at the rate of 12 liters per minute. The perfusate was pumped through the unit at the rate of 100 to 400 ml/min.



Soviet-made cellophane was used, with a pore size of 20 to 25 u and a total surface area of about 15,000 sq cm. In the Soviet apparatus the urea concentration was reduced from an initial value of about 400 to 250 mg% after 6 hours; the distilled water was changed after 3 hours. Using the French "Usifroid" apparatus, urea was reduced from about 500 to 250 mg% in 6 hours, without changing the dialyzing solution. Thus, some 100 g of urea were removed during the first 6 hours, or about 0.31 g per minute, equivalent to some 0.02 mg per sq cm of dialyzing surface per minute. Mathematical calculations by the authors claimed that this was about 90% of the theoretical maximum for this system under the present Soviet state of the art.

These experiments led to improvements in the apparatus (and we hope in the training of technical assistants). The improved apparatus was used clinically on 39 patients for a total of 61 dialysis sessions. Of these, 29 cases (74%) recovered. The conditions ranged from septic abortion (11 cases), transfusion reactions (7 cases), and mercurial poisoning (5 cases) to compression syndrome (1 case) and arenal anuria (3 cases). Recovery in these conditions was 82, 72, 60, 100, and 0%, respectively. It should be noted that this model has a "dead volume" of only about 420 ml, in contrast with those of 800 to 1,200 ml in Western models. Failures in this group were ascribed to insufficient familiarity of physicians with the work and capabilities of the renal hemodialysis centers. Most of the patients were referred to the centers in either terminal or near-terminal states.

### Artificial Circulation

We have made a somewhat arbitrary choice of the term "artificial" circulation for the title of this sub-section, in preference to the more generally used term "extracorporeal" circulation, and some explanation seems necessary. As it appears in translations of Soviet literature and is interpreted by the writer, "artificial" circulation refers to the entire area of cardiovascular function and its duplication or replacement. Extracorporeal circulation, on the other hand, is used by the Soviets to denote the apparatus and equipment by which the heart is temporarily bypassed, and circulation of the blood, including its oxygenation and other respiratory functions, is performed outside the body. This term is therefore contrasted to "intracorporeal" circulation, and the two terms together make up the sum total of the area of "artificial" circulation. The latter generally connotes the goal of this particular field of prosthetics--namely, an intracorporeal pump which replaces or substitutes for the biologic heart.



At its present stage of development, the artificial heart is only emerging from the design stage, with a few experimental models having been used in dogs in both countries. The majority of experimental and clinical work in this area is directed toward one or another aspect of "artificial" circulation--that is, extracorporeal circulation, artificial heart valves, and electrocardio-stimulation. In working to replace or restore any one of these, it has generally been assumed that the remaining functions are still performed by living tissues, or that the potential to perform them is still available, provided that the third condition is corrected by some means. Thus, the extracorporeal circulation bypasses the heart until the latter can again resume its function as a "pump," using (usually) its own valves and pacemaker. Artificial heart valves generally replace defective living tissues, but still rely on the integrity of the rest of the heart, including the pacemaker, as well as on the peripheral vessels, for their usual functions. Similarly, an electric cardiostimulator depends on the potential myocardial contractability of the intact living heart and circulatory system, with normal or artificial heart valves. But this view may change drastically in those instances where two or all three of these functions are replaced by prostheses. For a further discussion of the pacemaker, see below. Suffice it to say here that artificial heart valves, however essential they may be to the function of the living or the prosthetic heart, nevertheless play a basically passive role in blood circulation. They open and close in response to the flow of blood, regardless of how the blood may be propelled through them. One could envision, of course, the development of artificial valves equipped with miniaturized transducers and servomechanisms which would respond to pressure gradients or other hemodynamic parameters by actively opening and closing, even in a semiquantitative manner. But this appears to be beyond our present state of the art.

Plastic hearts designed by Soviet scientists before the end of 1963 enabled dogs to survive up to 14 hours (56). No details are given. More recent Soviet models (57) are described in some detail. At least two Soviet "artificial" hearts are based on the following principles and specifications. The systolic volume is regulated by the venous pressure; when the latter is 0, blood is pumped at a rate of 500 ml/min. When the venous pressure rises to 15 mm Hg, the stroke volume is increased to 2,800 ml/min. The systolic pressure in the aorta is maintained at 140 mm Hg, and the diastolic pressure at 90 mm. No design or construction details are available. These types were implanted in dogs after removal of their hearts, and some animals survived up to 32 hours.

According to Timakov (56), the first artificial circulation device in the Soviet Union was created in 1924 by S. S. Bryukhonenko and S. I.

Chechulin. This device was used to maintain life in the severed head of a dog. In 1928 the first Soviet operation using this apparatus was performed on the heart of a dog by N. N. Terebinskiy.

The first successful human open-heart operation in Russia, using an artificial blood circulation apparatus, was performed by Prof A. V. Vishnevskiy in 1957 (58). The apparatus was constructed, as is most other medical and surgical equipment in Russia, by the Scientific Research Institute for Experimental Surgical Apparatus and Equipment. Since that time several other apparatuses of varying design have been developed at the Institute of Cardiovascular Surgery and other facilities. The Soviets believe that the development of such apparatuses and the analysis and evaluation of circulatory and respiratory pathophysiologic data accumulated in related studies will pave the way for complete replacement of the heart by an artificial organ. This replacement is regarded as purely functional, that is, the subject's heart will not be removed but only bypassed as required. Thus, the Soviets' use of the term "artificial" heart, at least in the current context, really only refers to an external or possibly internal heart-lung or pump-oxygenator apparatus. As late as 1963 American and other Western efforts in the design and construction of compact intracorporeal pumps to replace one or both ventricles in dogs had not yet attracted the attention of Soviet investigators (53).

In his discussion of the accomplishments of the Academy of Medical Sciences of the USSR during its 20 years' existence, Prof Parin (59) listed some of the tasks and accomplishments of the Institute of Surgery imeni A. V. Vishnevskiy. These included "dry heart" operations with the use of an artificial blood circulation apparatus; hypothermic operations using cooled blood or other perfusates circulated through the coronary arteries; isolated artificial blood circulation of the brain under hypothermia, permitting surgery of the isolated heart for as long as 20 minutes. The Institute also claimed the first prosthetic valve of the pulmonary artery; it did not, however, claim the first success.

Research conducted at the Institute of Cardiovascular Surgery of the Academy of Medical Sciences of the USSR included, among others, work on artificial circulation and valvular prostheses (60). Between April 1960 and September 1964, Burakovskiy et al. (61), working in the Department of Congenital Heart Defects and the Pathomorphology Division of the Institute, performed 475 open-heart operations, using extracorporeal circulation in 321 of them, with and without hypothermia (28 to 33 °C). Three apparatuses were used, but the results were not



differentiated: the Melrose and Lillehei-DeWoll systems, and the Soviet AIK-63 model. Of 246 patients operated on, 86 (35%) died. The mortality rates for the years 1960 to 1963 were 46, 44, 32, and 28%, respectively. Most of the deaths were attributed to the severity of the patients' conditions just prior to surgery--viz., tetralogy of Fallot and intraventricular septal defect accounting for 49 (57%) of the deaths. Cerebral anoxia and hypoxia from various causes accounted for 27 (31%) of the deaths. The remaining 10 deaths (12%) were due to sepsis, hemolysis, and other causes. Some of the deaths in the severest surgical conditions were admittedly due to technical errors. Acute blood loss, due to excessive heparinization and lack of care in suturing accounted for 12 deaths. Air embolism, due to faulty operation of the apparatus, occurred in 2 patients.

Kolesov et al. (62) noted only minor morphologic and functional changes in the blood during perfusions of 19 to 48 minutes, using the AIK-59 and ISL-2 Soviet models of the extracorporeal circulation apparatus. The AIK-59 and -60 machines required 3 to 3.5 liters of donor blood. The heart-lung machine designed by Balyezek in Kupriyanov's clinic required 2 to 2.5 liters. That designed by N. M. Amosov's clinic required only 750 ml. Newer Russian models are said to require only 300 ml (57). It was observed that the use of the smaller quantities led more frequently to hemolysis, while in a series of 32 patients using the AIK-59 and -60 machines no hemolysis was ever noted, using either fresh blood or donor blood stored for 16 to 18 hours at 4 to 6 °C. In a few isolated instances the blood remaining in the apparatus was afterward used for transfusion to postoperative and burn injury patients, apparently without incident (57a). The blood was removed from the apparatus under sterile conditions, but penicillin was added before further use. The high oxygen content of "used" blood would appear to make its use for transfusions highly desirable in some cases, since it resembles arterial blood. One must assume that the nature of the condition for which the blood was initially used, as well as such factors as the medication administered to the perfused patient, and the presence or absence of immunologic, infectious, inflammatory, neoplastic and other conditions would be considered before using such blood.

The AIK-59 apparatus mentioned in the previous paragraph had a circulation time of 5 liters per minute at up to 95 to 96% oxygen saturation. Hemolysis did not exceed 20 to 30 mg%. The perfusion pump allowed independent and smooth regulation of stroke volume from zero to maximum, and of pulse rate from zero to 100 per minute. Extended movement of the pump diaphragm caused excessive turbulence of the blood flowing through



the apparatus; moreover, the diaphragm was made of rubber. The absence of a manual pump drive complicated its assembly and preparation for use, through the need to open the housing to set the pistons in proper position. The blood flow section was made of poor heat-conducting materials. Because of the pulsating nature of its operation, the AIK-59 pump could not always withdraw the blood from the coronary arteries.

The new AIK-60 model was designed to eliminate or correct these undesirable features. A large diameter diaphragm of polyvinyl chloride replaced the rubber one; movement was restricted to  $\pm 5$  mm. A manual drive mechanism was installed to permit easier assembly, and to insure operation in case of power failure. A warming device was installed on the oxygenator. A special vacuum pump was added to remove coronary blood directly to the oxygenator. The mechanical pulse regulator of the AIK-59 was replaced by an electric regulator, which eliminated knocking and other objectionable noises in the earlier apparatus (63).

In April 1965, Babskiy and Parin (64) cited a number of prosthetic devices currently being used in Soviet medical and surgical practice. Among these are equipment for artificial respiration, artificial circulation of blood and other fluids, including pumps, oxygenators, and heat exchangers, artificial hemodialysis, electric stimulation of the heart and other organs, and others. They also cited tests conducted on implanted devices, including the artificial heart used in dogs, and various electronic devices which use as their sole source of energy that liberated by the tissues themselves. Some of the latter will be discussed in the following sections.

There are some indications (65) that the Chinese are using extracorporeal circulation machines, but no details are available at this time.

Kolesnikov et al. (66) have recently reviewed "foreign," chiefly American research in the use of extracorporeal circulation during surgery, as well as American developments in artificial prostheses of the aortic valve. This is an excellent review of American investigations and progress in these two areas, the more so because it is presented without bias, criticism, or comment.

The use of extracorporeal circulation for regional perfusion of tumors and other conditions for chemotherapeutic treatment has been recommended by Parin and Babskiy (53, 57). This technique is being

used in several Western countries, namely, the United States and Japan, with and without hypothermia (67). Perfusion of tumors is localized through the lymphatic circulation.

### Artificial Heart Valves

The valves of the heart are all considered to be passive in operation, responding only, as mentioned elsewhere, to the flow of blood against them. It is not, however, beyond the realm of conjecture that further elucidation of the microscopic or ultramicroscopic structure of myocardial innervation may indicate that valvular function can be correlated with other parameters of cardiac activity--e.g., myocardial biocurrents. At present, the job of American and Soviet surgeons is to replace the hemodynamic functions of these valves as closely as possible.

Using flow models developed at the Institute of Cardiovascular Surgery, Kuzmina (68) tested various types of heart valve prostheses. She determined that ball, single-leaf, and triple-leaf designs with the same internal diameters had essentially the same carrying capacities. Wing valves of the same diameter had a markedly lower capacity. The materials used for construction of the valves (in these instances a series of natural and synthetic rubbers) also affected resistance to flow, in relation to the rigidity and inflexibility of the materials. Kuzmina noted that one of the disadvantages of leaf valves is delay during closure. This had been observed in the United States several years ago, and accounts for the current widespread use of ball-type prostheses in this country. In vivo experiments on dogs at the Institute of Cardiovascular Surgery were apparently beset with technical difficulties at that time. Four of 15 dogs died almost immediately after surgical implantation of the prostheses, due to leaves sticking in the ring, rupture of all 3 leaves after 1 1/2 hours, and defects in one of 3 leaves. Mitral valve replacement was performed using a metallic housing with a teflon ring and a polyurethane ball. In almost all cases this operation was successful; the pressure gradient across the implanted valves was 0 to 4 mm Hg. The leaf-type valve consisted of a teflon housing with a flexible polyurethane leaf. Examination of the exercised hearts with implanted prosthetic valves showed the three-leaf and ball types to be most satisfactory. The size of the ball valve, however, caused trauma to adjacent tissues and reduced the effective left ventricular volume.

The Institute of Cardiovascular Surgery has successfully replaced aortic and mitral valves in human subjects, using the ball-type pros-



thesis designed by Starr and Edwards in the United States. The Soviets have also developed a prosthesis for pulmonary valve replacement. At the Eighth Scientific Session of the Institute, held in May 1964, Litmanovich (33) reported that the use of lobe--i.e., leaf, valves for mitral valve prosthesis, as observed by Akimov and Sidorenko in Kiev, was not feasible, and that only ball valves were in current use in Russia. The number of patients operated on for aortic valve replacement in the Soviet Union was still very small by the end of 1963.

In 1963, Krivchikov (69) and others in the Clinic of Heart Surgery of the Ukrainian Institute of Tuberculosis and Chest Surgery designed a leaf-type prosthesis for replacement of the mitral valve. This development evolved from the shortcomings of existing ball-type prostheses--viz., large mass and inertia, audible performance, rigidity, and mismatch of intake and outlet areas. The new prosthesis was built on a stainless steel frame resembling four tangential rings; the largest ring corresponded to the valve ring, while the others formed the edges of the cusps. The frame was sheathed in teflon felt up to the junctures of the cusp frames with one another. A teflon felt tube was then inserted into the valve ring up to the level of the cusp junctures and then everted and folded over the outside of the frame. The tubing was cut to the upper level of the cusp frames, and the inner and outer edges of the tubing were stitched together with lavsan thread. The double-thick tubing was then fastened to the frame by stitching it around the cusp frames, also with lavsan thread. The inner borders were then cut, leaving 3 double-walled teflon felt cusps. After shaping the leaves on a mold, the prosthesis was stabilized by heating at 220 °C for 20 minutes. A set of 3 prostheses was prepared prior to each operation, with valve ring diameters ranging from 26 to 35 mm. The device was first used with apparent success in 1963 by Prof N. M. Amosov on a 14-year old girl suffering from congenital mitral valve insufficiency.

Krivchikov (69a) pointed out several disadvantages of spherical ball prosthetic valves: the ball, because of its inertia, may still be in the path of the blood flow from ventricle to aorta even when the valve is closed (sic). Furthermore, since the valve is tilted toward the intra-ventricular septum to which it is sutured, the metallic frame may push against the septum and damage the bundle of His; and, as mentioned elsewhere, the ball, because of its size, may reduce the effective ventricular capacity. To overcome or reduce these disadvantages, Krivchikov and his colleagues have more recently (69) designed a valve using a spherical segmental flap of silocone rubber. One can picture a



slice through a small rubber ball. The segmented ball valve is set in a stainless steel frame designed to prevent the segment from turning over or moving about (fig 1). the base is of stainless steel, with a teflon collar. In the figure, R (radius of segment) = 13 mm; D (diameter of hydraulic opening) = 20 mm; H (height of valve) = 21.5 mm; and h (path of valve) = 7.9 mm. Sets of valves are prepared as usual, keeping the ratio  $R/D = 13:20$ . This valve is said to be applicable to the replacement of mitral, tricuspid, and aortic valves. The prosthesis weighs between 12.9 and 13.9 g, in contrast to 20.5 and 21.4 g for Russian and American ball-type valve prostheses, respectively. No clinical data are available at this time.

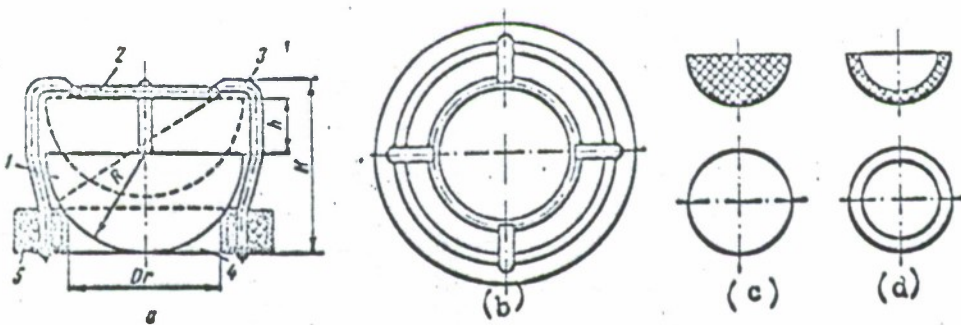


Figure 1. Diagram of a spherical-segmental cardiac valve

a--side view; b--top view; c--one-piece segmental flap;  
d--light-weight flap; 1--flap; 2--ring; 3--bows; 4--base  
of valve; 5--collar for valve to grow into.

### Cardiac Pacemaker

The history of cardiac electrostimulation dates back to the beginning of the 19th century, when Italian scientists attempted to revive the heart of a decapitated man through the use of an electric current. In 1850 the technique was used successfully on a patient suffering from syncope under chloroform anesthesia. Further developments were noted from time to time since then up to the present day (70). The principle,

therefore, is not new. However, the approach to the problem during the past 15 years or so has been directed toward more stringent limitations of the electric parameters of such devices, in consonance with those of normal myocardial electric activity. Moreover, the advances in electronics and component miniaturization since the end of World War II have stimulated research and development in this area by permitting the design and construction of components small enough for intracorporeal implantation. Electrocardiostimulators consist, basically, of a power supply, a pulse generator, and a set of electrodes. Several different principles and designs have been used for each basic component. The only part of this system that must be attached to the subject, under our present state of the art, is the receiver, which is generally attached directly to the myocardium which it stimulates. This general type of apparatus was used in the United States as early as 1953, for prolonged electrocardiostimulation in patients with Adams-Stokes disease.

One of the earliest Soviet models of electrocardiostimulator was designed by Bredikis (70a) in 1959, in collaboration with an electronics engineer. The apparatus operated from mains current. It generated square-wave pulses at rates from 18 to 200 per minute, with a pulse duration regulable between 1 and 60 milliseconds. The voltage and current were adjustable between 0 and 170 v and 10 and 60 ma, respectively. The device weighed about 1.5 kg. In 1960 Bredikis and Kazakevichus (71) designed a portable instrument weighing only about 100 g, which could be carried in one's pocket. Pulse frequency and duration were 45 to 180/min and 6 to 7 milliseconds, respectively, with a voltage of 4 v and a current of 20 ma. Metal disc electrodes 2.5 cm in diameter could be applied to the chest wall, or needle electrodes could be inserted into subcutaneous tissue or muscle, or directly into the myocardium. Experiments with dogs showed no harmful effects of prolonged (4 to 5 hours) electrostimulation on cardiac activity. The power supply consisted of 4 zinc-silver batteries maintaining constant performance up to 100 hours. The device was used with satisfactory results in the emergency clinic of the Kaunas Medical Institute.

One of Elmquist's early cardiostimulators, used for a patient in London in 1960, was about 6 cm in diameter and 2 cm thick, and covered with a biologically inert plastic. The stimuli from this device, implanted in the subcutaneous tissues, had a voltage of 2.5 v, duration of 10 to 12 milliseconds, and a frequency of 70 to 80/min. The instrument operated for 7 to 8 days on a small battery, after which the latter was recharged in the hospital through a large induction coil placed directly over the implanted unit. The patient was ambulatory and being handled as an out-patient.



Elmquist's second instrument operated on a small mercury battery, which increased its operating time to about 3 years. The current was reduced to microamperes. The battery and stimulating unit were combined in a single component, which was implanted subcutaneously and could be replaced under local anesthesia.

Grigorov et al. (72) described the implantation of electrodes in the left ventricular wall and of the electrostimulator in the subcutaneous tissues of the left upper abdominal wall in a patient with total atrioventricular block. The instrument was not described.

The Soviets (58) claim to have developed a pacemaker which operates successfully up to 3 years. They claim to be developing electrocardio-stimulators with power supplies for many years. Torok et al. (73) in Hungary have described a cardiac pacemaker which operates at high radio frequencies; this device has been used to maintain cardiac activity in dogs, and in one human subject with cardiac arrest. By November 1963, over 2,000 patients were reported to be "wearing" electrocardiostimulators of Soviet design.

In 1964 Savelyev et al. (74) reported on the use of a Soviet electrocardiostimulator which had been developed at the Scientific Research Institute of Surgical Instruments and Equipment in 1962. The device had been designed and constructed in response to the absence of similar domestic products and the limited importation of foreign products. The instrument was apparently based on the work of Senning in Sweden (75), Chardak et al. (76), Zoll et al. (77), and Kantrowitz (78) in the United States, and Glass et al. (79) in England. It consisted of a blocking generator, follower simulator, and power pack. It generated a biphasic current at a rate (sic) (pulse duration--Ed) of 1.5 milliseconds. The stimulating rhythm was set at 55 to 65/min, at a voltage of 6.5 v. The mercury-mercurous oxide batteries were "guaranteed" for 3 1/2 years. The entire device was a flat cylinder 5 cm in diameter and 1.5 cm thick, and weighed about 120 g. The housing was sealed with silicone rubber which did not produce inflammatory reactions. The instrument was implanted in the left subcostal subcutaneous tissue or, in women, in the left retromammary space, under local anesthesia. The device was tested in 17 acute and 7 chronic experiments in dogs, and has since been used successfully in 3 human subjects.

One of the prerequisites for the construction of one mode of an artificial heart is a set of electronic components which can simulate the



the activity of the normal heart. Such a device was designed in the Soviet Union as early as 1951 by Frank (see page 11), using the principle of dipoles to simulate the normal electrocardiogram (80). A more elegant device, capable of simulating both normal activity and cardiodynamic disturbances and imbalances, was constructed by Akulinichev et al. (80). One of the technical problems related to developments in electrocardiostimulators is the extension of its implantation life, that is, its ability to supply a constant, reliable, and continuous output of power over prolonged periods. This problem is related to a large extent at the present time to battery technology. One way of avoiding this problem is the use of internal circuits that will permit the recharging of the batteries without removing them from the subject's body. Both types of pacemakers are in use and under further developments in many countries, including the United States, Russia, England, and Australia (67). Cywinski and Stopczyk (67) have recently designed a cardiostimulator controlled by ECG limb lead impulses. This technique involves major surgery. The approach, however, is intriguing in that it permits the heart to re-establish its own normal rhythm and wave form.

Recent information (57) indicates that the Soviets are interested in still another type of electrocardiostimulator. Since cardiodynamic activity results in movements of tissues both within and outside the cardiovascular system, it is theoretically possible to use these movements or other changes as a source, not only of power but also of normal cardiac rhythm. One such instrument using this principle has two piezoelectric (pressure-sensitive) transducers attached to the aorta. Pulsations of the aorta due to the passage of blood cause the transducers to generate an electromotive force which is fed to the pulse generator. The latter generates stimuli lasting 1.6 milliseconds, with a voltage of 1.6 v. In another device the transducers are attached to the diaphragm, presumably at the point of attachment to the pericardium. Both types have been used in dogs; no work involving human subjects in Russia has been forthcoming.

### Biostimulation

In the United States, physiology is accepted as a basic biologic science, without too much distinction from biochemistry and biophysics. In the Soviet Union, on the other hand, physiology is recognized as being composed of these two sciences--viz., physiologic chemistry and physiologic physics. This concept is substantiated by the fact that from top to bottom of the Soviet hierarchy of biologic and medical investigation and practice, the term "physiology" rarely appears. Moreover,

separate institutes in the Academies of Sciences and Medical Sciences are devoted exclusively to biochemistry and biophysics.

The materialistic concept of animal organisms, which only the most stubborn diehards still deny, demands that we treat and investigate the materials of the human body as we would any other materials--viz., according to the laws of chemistry and physics. In this context we refer to biochemistry and biophysics. In the Soviet Union, whatever is not biochemical in content must be biophysical. This concept is still very slow to gain acceptance in the United States.

The Soviets have accepted completely the idea that in order to investigate, analyze, simulate, and otherwise apply the laws and interrelationships of biophysical phenomena--movement, motion, blood flow, cardiac activity, renal filtration, gastrointestinal peristalsis, to name a few--the laws and modes of biophysics must be studied and applied. For a particular biophysical function or activity, a particular branch of biophysics can usually be identified, and this is the one to be studied.

(Note--the field of biophysics is divided into biologic sciences completely analogous to the areas of physics--viz., biomechanics, biomagnetism, bioacoustics, biooptics, bioelectricity, and bionucleonics, or radiation biology. Each of these areas is concerned with the corresponding physical phenomena as they occur in or act on the body. Note further that the energy for all biophysical function, which can be studied under the special heading of bioenergetics, has as its source a series of biochemical reactions. This intimates in a small way the close relationship between biophysics and biochemistry.)

The remainder of this section is devoted to one or possibly two areas of biophysics--biomechanics and bioelectricity, but mainly the latter. Our interest is also centered in the broad realm of bioenergetics. All muscle movement is under the control of bioelectric currents conducted from the brain to the nerve(s) innervating the particular muscle or muscle group. Therefore, reasoned the Soviets, in order to stimulate these muscles or to move the living part or corresponding prosthesis, it is most logical to use those biocurrents from the brain which would normally cause the part(s) to function. However, bioelectric potentials of nerves leading, for example, to arm muscles which flex and extend the fingers and elbow joint, and pronate and supinate the forearm are extremely small, much less than the 20 to 40 uv required to activate the control mechanisms of current prostheses. The potential carried by the nerve,



however, causes a series of biochemical reactions within the muscle which releases sufficient energy to produce muscular contraction. It is this energy which can be measured, recorded, and transmitted to control devices and amplifiers. This biochemical conversion of bioelectric energy from nerves to biochemical energy in the muscles, or myocurrents, constitutes a biologic amplifier, through which the weak neuropotential is raised to a measurable myopotential. It is this potential which the Soviets have used as the basis for their development of biophysical control systems.

The Soviets define bioelectric control rather broadly, in terms of the use of electrochemical signals transmitted to various parts and organs of the body, including the brain itself, to bring about various effects on biologic functions. In actual fact, this concept is not new (see page 38), but Russian applications of this principle have opened broad new vistas for investigation and potential exploitation. In 1949, for example, Soviet experiments were conducted with mice having electrodes implanted in various cerebral areas; these were attached to small radio receivers placed on the bodies of the animals. Signals from laboratory apparatus then elicited various sensory and motor reactions (81). The current use of electric shock therapy for various psychopathologic conditions is a form of bioelectric control, although one could not say whether they would include this "shotgun" technique under this concept. Another more recent outgrowth of these experiments has been the development of so-called "electroanesthesia." Experiments with the latter in the United States showed satisfactory anesthesia in only about 50% of cases. In Russia, on the other hand, this technique is being used routinely for general anesthesia in about 2 to 3% of all surgical procedures. Another nebulous area of bioelectric control is so-called "electric sleep." None of these areas is within the scope of the present discussion.

It was only a step from the use of laboratory currents for stimulation such as that mentioned in the preceding paragraph, to the use of biocurrents themselves. The Soviets have identified the area of investigation and application of bioelectric currents taken from either the subject or from a "donor" for purposes of physiologic control, as biostimulation. Leaving aside semantic considerations, biostimulation is the direct or indirect use of biocurrents for the control of biologic or nonbiologic functions. Direct biostimulation involves the transmission of bioelectric signals picked up from the donor to a recipient subject or prosthetic device or other instrument, either with or without amplification. Indirect biostimulation requires the use of a recording instrument, usually a magnetic tape recorder, for transcription of the bioelectric signals, to be used as indicated above. The latter technique has certain advantages.



It allows one to store signals until the most convenient time for their use. It allows the same signals to be used repeatedly, and it permits one to operate several devices or to stimulate several subjects simultaneously. The latter may be particularly useful in training and physiotherapy, being especially applicable to the strengthening and retraining of weak or paralyzed muscles and nerves, as frequently encountered in victims of various paralytic and debilitating conditions. Such therapeutic applications have been used in the Soviet Union since as early as August 1961 (82), when a prototype, the Biostimulat-1, was developed by G. F. Kolesnikov, V. I. Kiy, and A. M. Sirchen in the Department of Biocybernetics of the Computer Center in the Ukrainian Academy of Sciences. At that time the Soviets classified this application of biocurrents as biotics, since the recorded signals were the actual potentials recorded for human subjects.

In this regard, Petrova (83) discussed in detail the work of Prof Natalia Shenk at the Prosthesis Institute of the RSFSR. Shenk has been chiefly engaged in the development and application of physiotherapeutic devices for strengthening atrophied and paralyzed muscles through the use of biostimulation. She has developed a number of prosthetic limbs which use amplified myocurrents picked up from the amputation stump, which serve to operate the device (see below). As indicated above, the Soviets have used both types of biostimulation for physiotherapeutics and the operation of prosthetic devices. Our interest is almost entirely with the latter. This work has been done at several institutes in the Soviet Union since before 1957 (81), and culminated in that year in the development of a model artificial hand operated by biocurrents. Lest the Russians be given all of the credit, a group of British scientists in 1955 had built a similar system (84), referred to by the Soviets as a "grasping" device. Actually, this description is quite correct. The British have always been somewhat surprised at Soviet and other efforts in the modeling of "hands" and "fingers," without an alternative "hook."

In 1963, Parin and Babskiy (53) pointed out Soviet efforts in the field of implantation of devices for stimulating skeletal, smooth, and cardiac muscles, as well as various parts of the nervous system. They observed that one of the technologic goals in the design and construction of such devices was the use of the organism's own energy--i.e., biocurrents, as the source of power. In discussing means of artificial substitution of vital body functions, for example, they delineated four trends in the special case of artificial respiration: (a) rhythmic forced introduction and aspiration of air and other gas mixtures; (b) forced passive expansion of the chest cavity ("iron lung") by mechanical means;

(c) external instrumentation for blood oxygenation and carbon dioxide removal; and (d) artificial stimulation of paralyzed respiratory musculature. All of these means are apparently available in the Soviet Union, as well as in the United States, in either experimental or clinical programs. Thus, we have gas supply equipment through breathing masks, various forms of "iron lungs" and chest respirators, oxygenation and dialysis equipment related to artificial circulation apparatuses, and implanted electrode stimulation research, including actual clinical use of phrenic nerve stimulation.

### Orthopedic Apparatuses

In 1960, Soviet investigators at the Central Scientific Research Institute of Prosthesis and Prosthetics were working jointly with members of the Institute of Machine Science of the Academy of Sciences, USSR, to create an artificial arm which could be controlled by biocurrent amplification. This work was done in conjunction with that on the Biostimulat-1 instrument described above. Soviet prosthetics development at the present time is soundly but theoretically based on the principle of amplification of biocurrents. Thus, no matter how small a stump may remain after amputation, or even if there is no "stump" at all, sensor electrodes can be applied over the remaining muscle groups. Commands from the brain are transmitted directly to the same nerves and muscle as in normal persons, converted to myocurrents, and thence transmitted to wires, amplifier, motor, and parts (85).

The Soviets were aware of the complexity of the problems involved in working out and defining movement patterns of large numbers of muscles, such as those which control the fingers. These problems were apparently bypassed, for in 1963 22 persons were said to be using the Soviet prosthesis successfully for up to 18 months without breakdown. These early forearm prostheses had only two functions; to bend and unbend the fingers. Work was in progress at that time, and also at the present time, to develop a prosthesis which would permit rotation of the "hand." At the same time, a complete upper-extremity prosthesis was developed for shoulder amputees, the finger movements being controlled by biocurrents and the forearm movements--i.e., bending and unbending of the elbow, through the use of weights and pulleys, as in most conventional prostheses. The principle of biocurrent amplification was used in all of these appliances, and is now firmly entrenched in Soviet prosthetics technology. The Soviets did, however, carry out some investigations on the development of a "pneumatic" hand. This



device, sometimes called the "Heidelberg arm," was developed in Germany, and seems to be preferred by German scientists to the Russian principle. The device is operated by means of carbon dioxide contained in a small tank under high pressure. Gas flow from the tank is regulated through biocurrent sensors located on the muscle stump, and again serves to operate only mechanisms to open and close the fingers. A single tank, usually located on the subject's back, serves to operate one or two prostheses, as required. Further developments along these lines are being carried out through research in both Germany and England.

Soviet trends in prosthesis construction have been toward the use of light metal alloys and plastics. Aluminum is used extensively. A Soviet prosthesis for the thigh weighs only 1 kg. A similarly light hip-joint prosthesis is also under study. Latex was originally used to cover the artificial hand and other appliances, but it has since proven to be insufficiently durable for this purpose. It has now been replaced by a series of polyvinyl films.

Russian designers of prosthetic extremities have complained that if their surgeons would not perform contractures of joint musculature, which renders useless certain muscle groups which could be used as a source of myocurrents, lockless apparatuses could be used more extensively, with consequently less restriction of function. The Central Institute of Prosthetics and Protheses has developed a double-hinged hip-joint prosthesis which allows flexion and extension within  $15^{\circ}$  of the vertical plane in walking, and also permits the subject to sit steadily. Assembly line production of hip and shank prostheses designed at the Leningrad Scientific Research Institute for Prosthetics was reported in 1964 (86). These prostheses were said to be light in weight, noiseless in operation, lined with polyurethane foam, and supplied with a near-natural foot. The article does not state whether or not these prostheses were bio-electrically controlled; however, the statement that they are noiseless would lead one to believe that they are not. The first artificial foot of Soviet manufacture was of black rubber and weighed up to 500 g. Newer developments with porous rubber allowed the weight to be reduced to 200 to 300 g. A tibial prosthesis has been developed which provides free movement of a multidirectional knee joint. Soviet surgeons formerly exarticulated the shin, thus losing knee joint function. The development of a multilink knee prosthesis, however, permitted higher amputation as required.

Prof B. Popov (87), director of the Central Scientific Research Institute of Prosthesis and Prosthetics, and himself a forearm amputee, has



stressed one of the fundamental changes which has taken place recently in the Soviet Union in the development of prosthetic appliances. Formerly, their development was entirely in the hands of clinicians and physiologists, which only permitted qualitative characterization of their requirements. The trend has now changed toward the accumulation of large amounts of quantitative data on all aspects of the various problems, chiefly those of biomechanics. Thus, the Soviets have developed nomograms for the construction of artificial limbs, based on weight, length, and other biomechanical parameters. Nomograms for lower limb prostheses were developed in 1963, and biomechanical calculations for upper extremities were begun in 1964. These appear to have been completed, if the development of the Soviet "below-the-elbow" prosthesis is any indication.

According to Kobrinskiy (81), the first artificial hand controlled by bioelectric signals was designed and constructed in 1957. Apparently the Russians were unaware at that time of earlier British work conducted in 1955 (84). The Soviet prototype was controlled by muscle currents which operated to flex and extend the fingers. The device was operated by the biocurrents of the user's own forearm muscles, and was thus a laboratory curiosity. The second prototype was designed to study operator trainability and to test the reliability and endurance of the components of the device itself. From these early developments, the Soviets proceeded to design a prosthesis of the forearm with bioelectric control. The signal source was the myocurrents from the group of muscles in the arm stump which, in the normal person, control the flexion and extension of the fingers. In the early types feedback was visual. Later developments included the incorporation of vibratory sensors into the metallic fingers, which returned signals to the electronic circuit that were proportional to the pressure exerted. The Soviets are also interested in "teaching" the hand of the forearm prosthesis to distinguish between heat and cold (56).

In his report on current trends in Soviet prosthetics developments (88), Popov made the following observations. By means of visual training through the use of an oscillograph, the Soviets are attempting to pick up and differentiate the functions of 6 different biocurrent signals from the muscles of a forearm stump and of 4 signals from those of an upper arm stump, and to control, respectively 6 and 4 forms of movement. Training for two movements, flexion and extension of the fingers, has been accomplished through this technique. The Soviets are also trying to miniaturize the amplifier and control units so that they

can be placed inside the prosthesis itself, instead of being worn on a belt at the waist or in one's pocket as at present. The Soviets envision the development of an entire series of prosthesis for both upper and lower extremities, capable of controlling any number of movements and thus affording the surgeon the opportunity to provide prosthesis at any level of amputation, according to the clinical requirements of the subject.

Prior to the end of 1963 (88), a forearm prosthesis with bioelectric control was made available for export by the Soviet All-Union Export-Import Corporation. The complete system consisted of a prosthetic forearm with bioelectric drive and shoulder socket, a charging device, storage battery, and amplifier unit. The following information was supplied by the export house. Flexion and extension of the fingers were independent of the position, that is, attitude, of the prosthesis. Biocurrents of 20 to 40 uv were sufficient to operate the driving mechanism. Several 20- to 30-minute training periods generally sufficed to acquire dexterity with the appliance. Only two amplification channels were available on the particular model described, the one for flexion and the other for extension of the fingers. However, it would be a relatively simple task to add at least two more channels for the simple tasks of flexing and extending the elbow joint, which is required for upper-arm amputees. The battery required recharging every few days, using ordinary mains current. The prosthesis was described as having a grasping force of 1.5 kg, yet one could pick up an egg without breaking the shell. The prosthesis weighed 800 g ( 1 3/4 lb ), while the amplifier and battery together weighed about 440 g ( 1 lb ). The Soviets claimed that some 125 patients were using this or a similar apparatus, including double upper-arm amputees. If the latter is true, this would confirm the fact that they have added two more amplification channels for flexion and extension of the elbow joint, unless these prostheses are either set in one position or another manually or operate at the elbow joint through the use of weights and pulleys, as in conventional prostheses.

While little interest in the Russian product has been evinced in the United States<sup>1</sup>, several models were acquired by English and Canadian

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<sup>1</sup>At this writing, only one American manufacturer of prosthetic appliances is known to be conducting developmental studies on a full upper extremity prosthesis. The particular model under investigation is being designed to pronate and supinate the forearm through bioelectric control. Aside from these experimental studies, one other American company is known to be in the process of manufacturing a forearm prosthesis with bioelectric control, developed in Italy. Details of this device are not presently available (89).



investigators and subjected to engineering and clinical evaluations. Canada, moreover, has sought to obtain a manufacturing license for the product from the Soviet government. Available photographs of the Russian model (90) indicate that this is a newer model, with certain distinct improvements in its design, specifications, and operation. The maximum grasping force was stated to be 15 kg, however, this is believed to be a misprint. Antagonistic muscle groups are used to supply the myocurrents to open and close the "hand." System response is quite rapid. Stopping and reversing are almost instantaneous. The entire device appears to be constructed of aluminum; it is very light, although its actual weight was not stated. The finger hinges correspond automatically to the metacarpophalangeal joints. The interphalangeal and phalangeodigital joints are not articulated (see below). There was no wrist joint in this model; however, later reports, both here and abroad, indicate that this feature has been incorporated into more recent models. The hand portion of the prosthesis is covered with a semi-elastic rubber layer which the Soviets claim will last about 30 days with ordinary use. Cosmetically it is very attractive. The entire device is held in place by a light leather strap which encircles the elbow just above the condyles. Older models employed a cumbersome cuff around the upper arm, which required the subject to pass the stump through the cuff and a hinged elbow joint. The usual stump sock has been eliminated, and the stump firmly contacts the prosthesis. Small windows in the upper portion of the prosthetic forearm permit precise location and adjustment of the sensing electrodes.

Clinically, the amputee finds the use of this device simple to learn and nonfatiguing in practice. The device has been used mainly on forearm amputees with previous experience for older, conventional types of prostheses. This type of patient has been trained to use relatively large amounts of energy to operate older types of prostheses, and the relief in using only isometric contractions is said to be quite astounding. Moreover, the amputee has the esthetically gratifying sensation of "grasping" with his "own" fingers. Furthermore, all of the fingers of the Soviet appliance move, while in conventional prostheses the 4th and 5th digits are generally immobile. None of the available literature is absolutely clear, but the general impression is that all four fingers are separately articulated but activated by a single applied myocurrent. The fingers are spring-loaded, so that each continues to "close" until it meets an object or force which opposes its continued movement. According to personal observations (89) of one Soviet model, the "thumb" orientation can be adjusted to some degree, so that it contacts the "fingers" either between the first and second fingers or the radial surface of the first finger.



## EVALUATION

General

The Soviet approach to the field of prosthetic devices follows naturally from their material concept of man and the world around him. In the "race for space" and in their avowed goal of attaining and maintaining an overall technologic stance that is superior to that of noncommunist nations, the Soviets have urgently and concertedly pursued those lines of investigation that will permit man and men to perform more efficiently and reliably, and with increased sensitivity, selectivity, speed, frequency, precision, accuracy, and so forth. It can be said, without fear of contradiction and almost without qualification, that the leadership of the Soviet Union is the most automation-oriented of any country in the world today. This situation is based on the recognition by Soviet leaders--scientific, political, and administrative--of the tremendous potential gains available through the application, in all fields and at all levels of endeavor, of principles of automation, cybernetics, bionics, and biotics. To accomplish this pursuit of machine technology, they have organized their scientific and technologic research programs in almost every area and at every echelon in accordance with the fullest exploitation of these principles. This is substantiated by the creation of the Scientific Committee for the Coordination of Complex Problems of Cybernetics, which insures that new developments in theories and principles of cybernetics and automation are applied wherever possible.

Developments in prosthetics in the Soviet Union are a spin-off from the results of investigations in bionics, cybernetics, and automation, regardless of the fact that many prosthetic appliances were already on the scene before 1948. At that time, however, there was no organized body of scientific principles, theories, and knowledge on which to base logical sequences of bionics research and prosthetics developments. The Russians were quick to apply this philosophy of dynamic control to their own concepts of scientific organization, management, and development.

The brief encounter of the Soviets with Western science and technology during World War II leads one to speculate that they were possibly impressed. They saw weapons, machines, and many other items of Western design and manufacture, including medical and surgical equipment, which were obviously far in advance of their own capabilities at that time. One can further speculate that their resolve to improve these capabilities and their own achievements, for example, in various areas

of machine and surgery is evident from the establishment, among others, of the Institute of Surgery imeni A. V. Vishnevskiy immediately after World War II. This and other related institutes not only gave impetus and direction to medical and surgical research, however poorly supported, but also laid down a structural organization and prototype within the framework of which could be placed those departments and laboratories which were dictated by related developments and requirements. Thus, we find here and elsewhere laboratories devoted to biocybernetics, bionics, prosthetics, and medical and surgical equipment in general. New institutes and facilities, with new or modified orientation and goals in these areas, spring up frequently in the Soviet Union, according to the exigencies of the moment.

### Alloplasty

Soviet developments in the investigation of new plastic materials for prostheses appears to be very slight in comparison to our own. The available Soviet literature indicates their strong preference for lavsan, a copolymer which appears to be related to dacron and terylene. It is known to be used in the form of woven material of various meshes. From Soviet reports, one is impressed with the general utility, or at least utilization, absence of carcinogenic activity, and absence of thrombosis when used for restoration and replacement of large blood vessels. When used for small vessels, however, it seems to offer no advantage over other materials. In general, the overall impression of alloplastic surgery is that one may be somewhat selective in the choice of chemical classes of compounds, insofar as biologic reactivity is concerned, and in the form and structure of individual prosthetic units with respect to the required properties of the tissue or part which they are meant to replace. The actual reaction in the body, however, seems to be purely a function of the relationships established between the prosthesis and the living tissues surrounding it. Thus, large vessels are easier to replace than small ones, while below a certain diameter, the degree of success is very low regardless of the prosthetic material and form used. Similarly, repair of hernia depends on the design and size of the prosthesis, rather than on the material of which it is made. It depends, also, on the extent to which it interferes with muscular activity. The Soviet concept of modifying the microstructure of prostheses to conform more to those of biologic polymers and tissues, or to provide more "biologic" properties is a hypothetical consideration which at the present time requires much more investigation before one can place it on a sound theoretical and practical basis.



In technique the Soviet surgeon as a whole is not well trained. He generally lacks experience, particularly in advanced surgical procedures. The basic reasons for this are beyond the scope of this report. Repeated statements of technical errors and deficiencies, however, both in surgery and in the use of corollary equipment, appear to bear this out. In brief, one might equate this deficiency to the relatively limited number of qualified teachers and demonstrators of good surgical techniques, who are far more interested in their own research as well as their own advancement than in sharing their knowledge. It may also be due, in part, to the rigid system of clinical surgery currently being practiced in Soviet clinics and hospitals. There are reasons to believe that young surgeons in Russia today remain in the capacity of assistants to chief surgeons far longer than they do in this country. Lastly, of course, the Soviet physician and surgeon are both impeded, hampered, misled, and frustrated by the lack of sufficient and serviceable surgical and medical equipment to meet even Soviet standards of practice today. (Dental equipment, for example, is made of such poor quality materials, metals, and alloys, that it frequently breaks down in actual use.)

### Prosthesis

As differentiated from alloplasty, prosthesis development in the Soviet Union is receiving somewhat more attention in both research and application. This is probably based in part on the fact that further developments in alloplasty at the present time await the synthesis and production of new plastics and new forms. The Soviets are doing very little original work in these areas. Prosthesis development, on the other hand, depends largely on the ingenuity of man, his inventiveness, and his ability to solve problems of bionics, of duplicating and replacing vital functions, and of biotics. Thus, prosthetics in the Soviet Union has received much theoretical impetus and technologic spin-off from bionics and cybernetics research being conducted in other areas.

Soviet artificial kidney (hemodialysis) apparatuses seem to be mainly modifications of our own and other western developments--e.g., France and England. Soviet cellophane appears to leave something to be desired, both from the point of view of its porosity and its possible toxicity. The latter, if true, doubtlessly reflects on the manufacturing process. Here, as elsewhere, difficulites and subsequent deaths are ascribed by the Soviets themselves to technical errors, which can only be blamed on poor equipment and poor training.



In the area of restoration and replacement of cardiovascular functions, the Soviets have begun to achieve a degree of success. Their work with artificial circulation systems, pumps, oxygenators, heat exchangers, and other components of extracorporeal circulation equipment follow basically that of the United States. Principles remain, as they must, the same. Apparatus design varies in conjunction with available components and materials, motors, pumps, dialyzers, and so forth. The Soviets' clinical use of this equipment seems to be on a par with our own, although perhaps their overall experience is not so extensive.

Soviet developments in artificial heart valves seem to offer some promise. The application of new materials and design principles is evident. Long-term postoperative evaluations are necessary for both the teflon flap prosthesis and the segmental ball valve. The specifications of the latter certainly appear to offer advantages over American developments at the present time, in terms of size, weight, function, and biologic reactivity.

The details of the Soviet intracorporeal pump, or artificial heart, are not known at this time. It has been used on dogs, which survived up to 30 hours. This is still considerably less than survival times currently attainable with American equipment and techniques. Moreover, the term "artificial heart" has been used by the Soviets to designate certain artificial circulation-oxygenation apparatuses which have been used to keep severed heads of experimental animals "alive." This type of sensationalism appears frequently in the popular Soviet press. In this connection, an "auxiliary" heart, which operates from the biostimulus of the real heart, has been developed in the United States.

### Biostimulation

Electrocardiostimulation devices have been another beneficial by-product of developments in other scientific areas, including electronics, miniaturization, bionics, and the special area of biostimulation. The Soviets' immediate requirements in the latter are in the realm of human amplification, namely, amplification or strengthening of normal human capabilities to compensate for or override certain deficiencies and inherent impediments imposed by current equipment, for example, in aerospace operations.

Soviet electrocardiostimulators are to all appearances equal to those of Western countries. They are light, compact, and apparently efficient.

All three major types--non-rechargeable battery, externally rechargeable battery, and externally controlled (implanted passive receiver and external transmitter)--are in use. The latter seems to offer excellent potential for long-term replacement with minimum maintenance.

In the area of bioelectric stimulation of paralyzed and weak muscles through physiotherapy and retraining, the Soviets appear to have had more experience than we in the United States. At the present time, only one instance is known to the writer (89) of physiotherapeutic procedures using biocurrents being practiced in the United States. This technique has also had an important offshoot in the training, for example, of Soviet cosmonauts and athletes. Few facts are available in the case of the former, but the implications and potential remain.

In the area of orthopedic appliances operated by bioelectric control, the Soviets appear to have stolen a march on the rest of the world, certainly on American workers. Little interest has been shown in this particular application of biostimulation by American manufacturers and designers, of prostheses, on the one hand because of the apparent high cost of production and marketing of such devices, and on the other because of the excellent present technology in conventional prosthetic appliances. There is no doubt in the writer's mind, however, that we have the knowledge and technology to make sound and valuable contributions in this area, once we decide to enter the field. At the present time, major interest outside the Soviet Union appears to be centered in the British Commonwealth--England, Canada, and Australia. Chronologic analysis of available literature indicates that Soviet advances in this field have proceeded stepwise, from a simple opening and closing hand with a fixed wrist joint, and operated by the myocurrents of a normal individual, to a full-arm prosthesis with finger flexion and extension, and possibly bioelectric control of the elbow joint.

### Conclusions

Current Soviet research in alloplasty and alloplastic materials is concerned principally with refinements in the physical form and microstructure of available plastics, and with the discovery of new materials which have selective properties suitable to the particular purpose and function for which their use is intended. Soviet work in this area parallels or lags just behind similar American efforts and achievements. No spectacular breakthroughs are foreseen in this area in the near future, nor in the development of new principles of design, construction, and



application of artificial circulation and hemodialysis equipment and their appurtenances. Soviet work in artificial heart valves deserves special notice and monitoring, since they have brought forth prototypes and clinically applicable models of at least two new types, the teflon flap and the segmented ball.

The Soviets are presently developing pressure and temperature sensors for use in the fingers of the upper arm prosthesis, and are investigating means to provide pronation and supination of the forearm through bioelectric control. Similar developments are in progress with respect to lower limb prostheses. The retraining of amputees, especially those who have never previously used any other device, fitted with such prostheses is also foreseeable, by means of biocurrents recorded on magnetic tape during the accomplishment of various tasks by normal donors. These signals could then be played back, not only to amputees but also to normal individuals, after amplification, thus providing "instruction" in both the use of the prosthesis and the learning of tasks.

The Soviets have placed great emphasis on the exposition and application of biophysical and biochemical phenomena, and in certain areas have combined these admirably with principles and techniques of cybernetics developed in other fields of research. While these achievements and capabilities have and will continue to have immediate applications to the development of prosthetic devices, such as artificial cardiovascular appliances, renal models, and refined upper and lower limb prostheses, it is extremely likely that these developments will provide feedback to many other research areas. If the Soviets, for example, can define and analyze biocurrents from groups of muscles in such a way that individual myocurrents can be identified and in turn reapplied to the corresponding muscles in the same or other individuals, it would be possible to train large groups of entirely normal individuals for many tasks which presently require prolonged training periods. In addition, the Soviets will be able to draw on this broad substratum of biophysical and biochemical research and knowledge for the development and application of various esoteric situations, including the remote control, through the use of biocurrents either from muscle groups or directly from various nerves, of innumerable devices. The potential for such advances and applications in industry, public health, clinical medicine and surgery, and various aspects of aerospace operations is limitless, and requires only the ingenuity of scientists in all countries who are ready to accept the challenge and apply the principles of integration of many sciences to developments in any one of them.



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